

Advisory Committee
National Institutes of Health
Bethesda, MD 20892

NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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ERRATUM

In the Index for the NIH Guide for Grants and Contracts Vol. 14, No. 1, January 4, 1985, an error was made in placing an Announcement, Notice of Availability, Small Business Innovative Research Program, National Institutes of Health. The correct placement for this Notice of Availability should be under SMALL BUSINESS in the Index.

NOTICE

NIA APPLICANTS FOR SMALL RESEARCH GRANT AWARD (R03)

P.T. 34; K.W. 0710010, 0710030

NATIONAL INSTITUTE ON AGING

Effective with the receipt of Small Research Grant applications for the February 1, 1985 deadline, the National Institute on Aging will discontinue expedited review of these applications. Applications will continue to be accepted for the usual February 1, June 1, and October 1 deadlines. Earliest possible award date requested should be six months from date of submission.

It is no longer necessary to send advance copies of the NIA Small Research Grant applications to the Scientific Review Office/OPEA/NIA in view of the elimination of expedited review.

ANNOUNCEMENT

SOLICITATION FOR RESEARCH GRANT PROPOSALS

P.T. 34; K.W. 1007001, 0725005, 1007005, 1007008

ENVIRONMENTAL PROTECTION AGENCY

The U.S. Environmental Protection Agency (EPA), Office of Exploratory Research announces the availability of its Fiscal Year 1985 booklet entitled "Solicitation for Research Grant Proposals." EPA peer reviews and awards investigator initiated research grants in the areas of environmental biology, health, engineering, and chemical/physical measurements of air and water. For more information, call (202) 382-7473 or write to:

Office of Exploratory Research (RD-675)
Office of Research and Development
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

NOTICE

BLOOD, SERUM AND TISSUE DISTRIBUTION PROGRAM

YERKES REGIONAL PRIMATE RESEARCH CENTER OF EMORY UNIVERSITY

P.T. 36; K.W. 0780020, 0750010

DIVISION OF RESEARCH RESOURCES

The Yerkes Regional Primate Research Center provides a variety of tissue and fluid specimens from nonhuman primates for use in biomedical research. Specimens available include whole blood, serum or plasma; urine; tissues collected at autopsy or by biopsy; and cadavers following autopsy. Specimens can be provided fresh, in tissue culture media, frozen or formalin-fixed. Specimens are routinely available from macaques (primarily rhesus) and squirrel monkeys and are periodically available from chimpanzees, orangutans, gorillas and gibbons. A clinical history of the donor animal is available for each specimen. A nominal fee and shipping and handling charges are required.

This tissue distribution program is supported, in part, by the Division of Research Resources (DRR).

For more information, call or write:

Dr. Harold M. McClure
Associate Director for Scientific
Programs and
Chief, Division of Pathobiology
and Immunobiology
Yerkes Regional Primate Research Center
Emory University
Atlanta, Georgia 30322

Telephone: (404) 329-7742

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-10

THE ROLE OF HUMAN PAPILLOMAVIRUSES IN THE ETIOLOGY OF CERVICAL CANCER

P.T. 34; K.W. 1002045, 0715035, 0755030, 0715125

NATIONAL CANCER INSTITUTE

Application Receipt Date: June 1, 1985

I. BACKGROUND

Cervical cancer continues to be a major health problem in the United States. Invasive cervical carcinoma and carcinoma in situ represent 3% and 11% respectively of all cancers diagnosed in women. In the past, it had been suggested that this neoplasm and its putative precursor, cervical dysplasia, may be associated with viral infections of the cervix. Recently, a number of laboratory investigations have more strongly associated human papillomaviruses (HPVs) with cervical dysplasia and carcinoma. The presence of HPV DNA has been demonstrated in both cervical carcinomas and dysplasias. In one study, 70-90% of cervical tumors contained DNA from either HPV types 16 or 18. In addition, mild dysplasia appeared to be associated with the presence of DNA from HPV types 6 or 11. A number of established cervical tumor cell lines, e.g., HeLa, have also been examined and found to possess DNA segments of HPV type 18. HPV antigens and cytological markers have also been detected in a large percentage of dysplasias examined.

To firmly establish a viral etiology for cervical carcinoma and/or dysplasia, a study of the putative progression of primary genital papillomavirus infection to dysplasia and carcinoma is needed. Little is known about the temporal relationships or physiological mechanisms involved in such a progression. In order to carry out a study of the progression, more information is needed about the basic mechanisms of virus transmission, infection, replication and oncogenic transformation.

This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Etiology Research. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

II. GOALS AND SCOPE

The objective of this RFA is to stimulate basic research on the putative progression of HPV infections to dysplasia and carcinoma in human subjects and to relate this progression to the molecular biology of human papillomaviruses. Examples of such studies (which are not all encompassing) are 1) elucidation of the mechanisms of viral infection, replication and oncogenic transformation; 2) development of better in vitro model systems for HPV transformation and growth using either wild type or genetically engineered HPVs; 3) determination of the rates of regression or progression of cervical lesions in HPV infected subjects; 4) functional and structural characterization of HPV encoded proteins with particular regard to their role in oncogenesis and tissue specificity; 5) determination of the HPV types associated with specific categories of cervical lesions; 6) the nature of the host's response to HPV; and 7) the co-presence and possible involvement of other viral agents, such as HSV and CMV, with HPV in the oncogenic process.

III. MECHANISM OF SUPPORT

Awards will be made as research project grants. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years. Approximately \$850,000 will be set aside to specifically fund applications which are submitted in response to this RFA. It is anticipated that six to seven applications will be funded. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute (NCI), the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose. Non-profit and for-profit institutions within the United States may apply. All applications submitted in response to this announcement will be classified as new grants (Type 1). Future competitive renewal applications of grants funded under this RFA will compete with all other unsolicited applications received by the NCI. PHS grant policies governing regular research project grants, including cost sharing, apply to applications received in response to this request.

IV. INQUIRIES

A copy of the complete RFA describing the research goals and scope, the review criteria and the method of applying can be obtained by contacting:

Dr. Alan A. Schreier
Biological Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 9A-22
Bethesda, Maryland 20205

Telephone: (301) 496-1953

Inquiries concerning this announcement are encouraged and should be directed to Dr. Alan A. Schreier of the above address and phone number. The program would appreciate the opportunity to clarify any issues or questions.

ANNOUNCEMENT

OSTEOGENESIS IMPERFECTA

P.T. 34; K.W. 0705050, 0760005, 1003001, 1002019, 1002008, 0755020

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE OF DENTAL RESEARCH

The Musculoskeletal Diseases Program of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK), in cooperation with the National Institute of Dental Research (NIDR), is encouraging the submission of applications for research grants in osteogenesis imperfecta (OI) and related basic studies on the molecular structure of collagen.

Osteogenesis imperfecta is one of the most common forms of heritable disorders of connective tissue. It is a group of genetic disorders that result from molecular defects of connective tissue leading to a weakened skeleton with varying degrees of liability to bone fractures. Associated features in some, but not all, affected individuals include blueness of the sclerae, presenile hearing loss, dentinogenesis imperfecta, hyperextensibility of ligaments, and cardiovascular complications. Currently, classification for OI includes four types and two subtypes of clinical symptoms.

Collagen defects are generally accepted as major factors in causing OI. Structural or regulatory mutations have been shown within the gene coding for Type I collagen chains. These mutations lead variably to reduced synthesis of structurally normal collagen, to production of a molecule lacking the normal 2:1 chain ratio, or to the synthesis of a molecule containing a defective chain. In any case, tissues fail to accumulate sufficient normal collagen to provide an adequate scaffold for skeletal strength and for somatic growth. Other studies suggest that abnormalities of certain non-collagenous proteins, such as osteonectin, may also be present in OI.

This program is described in the Catalog of Federal Domestic Assistance No. 13.846, Arthritis, Bone and Skin Diseases Research and No. 13.842 - Craniofacial Anomalies, Pain Control and Behavioral Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Now that there appear to be several biochemical bases for OI, the NIADDK is seeking grant applications aimed at applying this information to larger groups of patients with this disease in its various forms. There is a need to determine the relative frequencies of each of the molecular defects that have been and will be discovered in OI. These studies can utilize either techniques of protein chemistry or molecular biology to characterize the primary biochemical abnormalities. It may be valuable to recreate the abnormality in cultured cells or animal hosts using gene transfer technology. Further use should be made of existing bovine models of OI.

Research applications could also focus on specific clinical applications of emerging new technologies. Novel and rapid methods to pinpoint mutations within the collagen genome and utilization of oligonucleotide probes to identify individuals carrying a specific mutation need to be developed. Families in which the presence of OI can be identified by a biochemical marker could be studied to determine the predictability of clinical manifestations, quantitative measures of bone mass, histomorphology of bone, and specific therapeutic modalities in OI patients at varying ages.

I. METHOD AND CRITERIA OF REVIEW

A. Assignment of Applications

Applications will be received by the NIH's Division of Research Grants (DRG), referred to an appropriate initial review group for scientific review, and assigned to the NIADDK or NIDR for possible funding. These decisions will be governed by programmatic considerations as specified in the DRG Referral Guidelines.

B. Review Procedures

Applications in response to this announcement will be reviewed in accord with the National Institutes of Health Peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants. Following initial review, the application will be evaluated for program relevance by the Advisory Council of the Institute to which the application is assigned. Review criteria customarily employed by the National Institutes of Health (NIH) for regular research grant applications will prevail. Approved applications will compete for available funds with other approved grant applications assigned to the NIADDK or NIDR.

C. Deadline

Applications will be accepted in accordance with the announced receipt dates for new applications (see receipt dates and review schedule in application kits).

D. Method of Applying

Applications for research grants should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. On page 1, item 2 the "yes" block should be checked and the phrase "ANNOUNCEMENT OF RESEARCH INTEREST IN OSTEOGENESIS IMPERFECTA" typed.

The original and six copies of the application should be sent or delivered to:

Applications Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact the following program directors:

Stephen L. Gordon, Ph.D.
Musculoskeletal Diseases Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building - Room 407
Bethesda, Maryland 20205

Telephone: (301) 496-7326

John D. Townsley, Ph.D.
Chief, Craniofacial Anomalies, Pain
Control and Behavioral Research Branch
Extramural Program
National Institute of Dental Research
National Institutes of Health
Westwood Building - Room 506
Bethesda, Maryland 20205

Telephone: (301) 496-7807

ANNOUNCEMENT

STUDIES ON EXERCISE PHYSIOLOGY AND AGING

P.T. 34; K.W. 0745030, 0710010, 1002034, 0710030, 0785055, 0201018, 0710095

NATIONAL INSTITUTE ON AGING

I. BACKGROUND INFORMATION

The National Institute on Aging (NIA) was established in 1974 to support and conduct biomedical, behavioral, and social research and training related to aging and to diseases and other special problems and needs of the elderly. The Exercise Physiology Section of the Physiology of Aging Branch, which is part of the Biomedical and Clinical Medicine Research Program of the NIA, has the responsibility for developing and supporting research which clarifies the influence of physical activity on the well-being of the elderly, both the healthy elderly and those afflicted by disease. To fulfill this responsibility, the major objectives of the Exercise Physiology Section are a) to define how the aging process affects adaptational biological responses to both acute and long-term physical activity and b) to assess how physical activity, particularly long-term type training, is involved in the promotion and maintenance of health and in the prevention of age-related diseases and disorders.

II. RESEARCH GOALS AND SCOPE

This announcement emphasizes the need for research in exercise physiology and exercise medicine as related to aging processes and age-related diseases and disorders. Of essential concern is the question "To what extent and under which conditions is the recommendation of physical activity for either healthy or disease-afflicted elderly medically reasonable?" Research directed to answering this question may be either basic or clinical by nature and may involve not only healthy human subjects and patients, but also suitable animal models. Approaches to this kind of research may range from cell biology to whole organism. The latter may include epidemiological studies on populations as well. To investigate the influence of physical activity on well-being in the elderly, it is imperative in research design to attempt to separate effects of primary aging from effects of both underlying disease and disuse atrophy.

Research areas of particular interest to the NIA include:

- o Studies to elucidate how mechanisms for biological adaptation to exercise, from system/organ level to cell/molecular level, are influenced by aging.
- o Studies to examine mechanisms through which regular exercise increases the capacity for work in the elderly and the relation this may have to health promotion and disease prevention.
- o Studies to assess the role and to define the mechanism of regular physical activity in preventing and/or reducing the extent of age-related diseases and disorders.

- o Studies to define quantitatively the criteria by which the prescription of exercise is safely formulated to fulfill individual needs of healthy elderly and of people in older age categories affected by various kinds of disease.
- o Studies to assess the role of acute and chronic exercise in the regulation of immunologic events involved in resistance to and recovery from infectious diseases in the elderly.
- o Studies to examine the mechanisms through which physical activity regulates behavior and psychosocial function in the elderly.
- o Studies to define the relationship between exercise and nutrition in providing independent and healthy years for the elderly.

III. MECHANISM OF SUPPORT

Support for this program will be the grant-in aid. Different mechanisms through which an award may be made by NIA are available and include: traditional Research Project Awards; Program Project Awards; New Investigator Awards; Academic Investigator Awards; Clinical Investigator Awards; Physician-Scientist Awards; Research Career Development Awards; and Small Grant Awards. The regulations (Code of Federal Regulations, Title 42, Part 52 and Title 45, Part 74) and policies that govern the research grant programs of the Public Health Service will prevail. The award of grants pursuant to this request for grant applications is contingent upon receipt of appropriated funds for this purpose.

IV. METHOD AND CRITERIA OF REVIEW

- A. Assignment of Applications: Applications will be received by the Division of Research Grants (DRG), NIH, and referred by the DRG to an appropriate study section for scientific review. Study section assignment will be governed by considerations specified in the DRG Referral Guidelines.
- B. Review Procedures: Applications in response to this announcement will be reviewed on a nationwide basis in competition with other applications received in the same review cycle, and in accord with the usual National Institutes of Health (NIH) peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section). Following study section review, applications will be evaluated by NIA's Advisory Council with respect to the adequacy of the technical merit review and the program relevance of the research proposed. The review criteria customarily employed by the National Institutes of Health for regular research grant applications will prevail.
- C. Deadlines: Applications will be accepted in accordance with the usual receipt dates for new applications (i.e., February 1/March 1, June 1/July 1, October 1/November 1).

V. METHOD OF APPLYING

Applications should be submitted on form PHS 398 which is available in the business or grants and contracts office at most academic and research institutions, or on form PHS 5161 for state and local governments. The phrase **"PREPARED IN RESPONSE TO NIA EXERCISE PHYSIOLOGY AND AGING PROGRAM ANNOUNCEMENT"** should be typed into item 2 of the first page of the application.

The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

VI. INQUIRIES AND CORRESPONDENCE

Inquiries about this program announcement and correspondence prior to submission of a proposal are encouraged and should be directed to:

William A. Kachadorian, Ph.D.
Chief, Exercise Physiology Section
Physiology of Aging Branch
Biomedical Research and Clinical Medicine Program
National Institute on Aging
Building 31 - Room 5C-27
Bethesda, Maryland 20205

Telephone: (301) 496-9350

ANNOUNCEMENT

BIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

P.T. 22, 48; K.W. 0720005

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) of the National Institutes of Health (NIH) announces the availability of postdoctoral fellowships to U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships biomedical, behavioral and health sciences.

Programs Available to U.S. Citizens or Permanent U.S. Residents:

ACADEMY OF FINLAND POSTDOCTORAL RESEARCH FELLOWSHIPS

ALEXANDER VON HUMBOLDT FOUNDATION POSTDOCTORAL RESEARCH FELLOWSHIPS

FRENCH NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH POSTDOCTORAL FELLOWSHIPS

NIH-FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH EXCHANGE PROGRAM

IRISH MEDICAL RESEARCH COUNCIL POSTDOCTORAL FELLOWSHIP

ISRAELI MINISTRY OF HEALTH POSTDOCTORAL RESEARCH FELLOWSHIPS

NORWEGIAN RESEARCH COUNCIL FOR SCIENCE AND THE HUMANITIES POSTDOCTORAL FELLOWSHIPS

SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS

SWISS NATIONAL SCIENCE FOUNDATION POSTDOCTORAL FELLOWSHIPS

VISITING SCIENTISTS PROGRAM OF THE NATIONAL SCIENCE COUNCIL, TAIWAN

The eligibility requirements of each program vary and this information is provided in each program's brochure which is available upon request. However, at a minimum, each candidate must have an earned doctoral degree in one of the behavioral, biomedical or health sciences and some postdoctoral experience.

The NIH is responsible for the scientific review of all applications except those that are submitted to the Alexander Von Humboldt Foundation and the National Science Council, Taiwan.

Applications to the Alexander von Humboldt Foundation and the Visiting Scientists Program for the National Science Council, Taiwan are available and are accepted

throughout the year. All other applications must be submitted by June 1, 1985. **Please note that this is a change in the receipt date for applications to these fellowship programs.** Applications to these two programs are available and are accepted throughout the year.

For those fellowship programs with a June 1 receipt date, application kits will be available from January 15, 1985 to May 15, 1985. The organization that provides financial support for each of the programs selects candidates for participation. While the maximum period of support for all programs is one year, the minimum period of support varies with each program.

All correspondence should refer clearly to the specific program of interest. For further information and fellowship application kits, please send a self-addressed label with your request to:

International Research and Awards Branch
Fogarty International Center
Building 38A - Room 615
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

SENIOR INTERNATIONAL FELLOWSHIPS

P.T. 22, 48; K.W. 0720005, 0404000

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) announces the availability of senior postdoctoral fellowships to outstanding U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of ideas and information in the biomedical, behavioral and health sciences. The types of activity that are supported by this program include collaboration in health studies, basic or clinical research, and the familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. This program does not provide support for brief observational visits, attendance at scientific meetings, attendance in formal training courses, independent research projects, or full-time clinical, technical or teaching services.

I. ELIGIBILITY REQUIREMENTS

Applicants must meet the following requirements.

- o Be a U.S. citizen or permanent U.S. resident.
- o Hold a doctoral degree in one of the biomedical, behavioral or
- o Have five years or more postdoctoral experience.
- o Have professional experience in one of the health, biomedical or behavioral sciences for at least two of the last four years.
- o Hold a full-time appointment on the staff of a U.S. not-for-profit institution
- o Be nominated by the dean or appropriate U.S. institutional official.
- o Be invited by a not-for-profit foreign institution.
- o Not be a previous recipient of a Senior International Fellowship.
- o Not be employed by the federal government.

II. APPLICATION AND SELECTION

There are now 3 receipt dates for Senior International Fellowship applications -- June 1, October 1 and February 1. **PLEASE NOTE THAT THIS IS A CHANGE IN THE RECEIPT DATE FOR THESE APPLICATIONS.** All applications are reviewed for scientific merit by the National Institutes of Health. Fellowship awards are

made for periods of three to twelve months. A fellowship must be activated within one year after receiving the Notice of Award and the starting date of the fellowship is set by mutual agreement between the fellow and the collaborator at the foreign host institution. Prospective applicants for the Senior International Fellowship Program may obtain information brochures from FIC. Fellowship applications are available from the FIC and may be requested only by the dean or equivalent institutional official. Information and fellowship applications are available from:

Senior International Fellowship Program
International Research and Awards Branch
Fogarty International Center
Building 38A - Rm 615
National Institutes of Health
Bethesda, Maryland 20205

For an expeditious reply, please send a self-addressed label with your request to the above address.

KEYWORD THESAURUS

The complete Keyword Thesaurus (Revised October 1984), a 44-page publication listing terms and codes to identify areas of interest for research and other types of sponsored programs, may be ordered from the National Technical Information Service. One of the goals of the Keyword Thesaurus project is to expand the number of agencies that will participate in coding their announcements of sponsored activities in order to facilitate distribution of announcements from many agencies to faculty and staff members who have interests in the specific areas listed. For those wishing to order, the price of a paper edition is \$10.00; and the price for the microfiche edition is \$4.50. NTIS Order Number is PB85-136893.

National Technical Information Service
5285 Port Royal Road
Springfield, Virginia 22161

As indicated in the January 4, 1985 issue of the Guide a listing of the codes and terms sorted in numerical order is presented with this issue. This may serve as a convenient look-up table for the NIH-relevant terms coded in each announcement.

A corrected copy of the January 4th listing of Keyword Thesaurus terms organized by 21 major groupings for use with the NIH Guide for Grants and Contracts may be obtained by writing to:

Dr. John C. James
Asst. Dir. for Special Projects, DRG
Westwood Building - Room 457
National Institutes of Health
Bethesda, Maryland 20205

0700000 HEALTH AND SAFETY/MEDICAL SCIENCES/BIOMEDICAL

0201011	Animal Care	0417000	Sociology
0201013	Animal Diseases/Pathology	0500000	Education
0201016	Animal Genetics/Breeding	0502000	Educational/Instructional Programs
0201018	Animal Physiology/Morphology	0502002	Alcohol Education
0201058	Veterinary Medicine	0502009	Dental Health Education
0202001	Food Additives	0502011	Drug Education
0202002	Food Analysis	0502017	Health and Safety Education
0401001	Anthropology, Cultural/Social	0502024	Medical Education
0403001	Adolescents	0502027	Nursing Education
0403004	Community/Outreach Programs	0502028	Nutrition Education
0403017	Volunteers	0502045	Pharmacy Education
0403019	Adults	0503007	Computer-Assisted Instruction
0403020	Infants	0503016	Instructional Materials and Practices
0404000	Behavioral/Social Studies	0503018	Learning Motivation
0404001	Addiction	0507002	Emotionally Disturbed, Educ.
0404003	Alcohol/Alcoholism	0507004	Handicapped, Education
0404004	Child Psychology/Development	0507005	Learning Disabled, Education
0404007	Death and Dying	0607010	Microelectronics
0404009	Drugs/Drug Abuse	0607023	Telemetry
0404019	Smoking Behavior	0607024	Ultrasonic Technology
0404020	Suicide	0705000	ANATOMICAL SYSTEMS/SITES
0404021	Surveys and Survey Research	0705005	Bone Marrow
0404023	Violent Behavior	0705010	Brain
0408006	Health Care Economics	0705015	Cardiovascular System
0410000	Linguistics/Philology	0705020	Connective Tissue
0410001	Language Acquisition/ Development	0705025	Digestive System
0411005	Risk Factors/Analysis	0705030	Endocrine System
0413000	Population Studies	0705035	Fetus
0413001	Demography	0705040	Immune System
0413002	Human Reproduction/Fertility	0705045	Lymphatic System
0413003	Migration	0705050	Musculoskeletal System
0413004	Population Biology	0705055	Nervous System
0413005	Population Control	0705060	Placenta
0414000	Psychology	0705065	Respiratory System
0414004	Clinical Psychology	0705070	Sensory System
0414005	Cognitive Development/ Processes	0705075	Urogenital System
0414006	Developmental Psychology	0706000	BIOMEDICAL ENGINEERING
0414007	Educational Psychology	0706010	Bioelectric Phenomena
0414011	Physiological Psychology	0706020	Clinical Engineering
0414012	Psychobiology	0706030	Medical/Diagnostic Imaging
0414013	Psychometrics	0706040	Physiological Controls and Systems
0414014	Social Psychology	0710000	DISCIPLINES/FIELDS
0414015	Behaviorism/Experimental Psychology	0710005	Adolescent Health
0414020	Psychodynamics	0710010	Aging/Gerontology
0415000	Therapy/Rehabilitation	0710015	Bioengineering

0710020	Biomechanics	0715115	Hypertension
0710030	Biomedical Research, Multidisciplinary	0715120	Immune System Disorders
0710035	Biotechnology	0715125	Infectious Diseases/Agents
0710040	Chemistry, Clinical	0715130	Mental Retardation
0710045	Drug Metabolism	0715135	Metabolic Diseases
0710050	Electrophysiology	0715140	Neuromuscular Disorders
0710055	Enzymology	0715145	Obesity
0710060	Immunochemistry	0715150	Pain
0710065	Immunogenetics	0715155	Perinatal Disorders
0710070	Immunology	0715160	Pregnancy Disorders
0710075	Immunopathology	0715165	Pulmonary Diseases
0710080	Medicinal Chemistry	0715170	Rheumatic Diseases
0710085	Neurophysiology	0715175	Safety
0710090	Nuclear Medicine	0715180	Senile Dementia
0710095	Nutrition/Dietetics	0715185	Skin Diseases
0710100	Pharmacology	0715190	Stillbirth
0710105	Psychopathology	0715195	Stress
0710110	Reproductive Endocrinology	0715200	Stroke
0710115	Reproductive Physiology	0715205	Sudden Infant Death Syndrome
0710120	Speech Pathology	0715210	Trauma
0710125	Transplantation Immunology	0715215	Tumor Immunology
0710130	Pharmacy	0715220	Venereal Diseases
0715000	DISEASES/MEDICAL PROBLEMS	0720000	EDUCATION/INSTRUCTION
0715005	Accidents	0720005	Biomedical Research Training
0715010	Arthritis	0725000	ENVIRONMENT
0715015	Autoimmunity	0725005	Environmental Health
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NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

CHANGE IN NATIONAL INSTITUTE ON AGING GUIDELINES FOR PROGRAM
PROJECT GRANT APPLICATIONS

P.T. 34; K.W. 0783015, 0710030

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA) Guidelines for Program Project Applications (**NIH Guide for Grants and Contracts**, Vol. 12, No. 4, April 22, 1983) are revised effective April 1, 1985 to delete the limitation on level of funds requested and consecutive years of support.

Teaching Nursing Home program project applications must also be consistent with these overall guidelines for program projects.

ERRATABIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

P.T. 22, 48; K.W. 0720005

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

In the January 4, 1985 edition of the NIH Guide for Grants and Contracts Vol. 14, No. 1, an error was made in the last sentence of the first paragraph. The correct sentence should read as follows:

The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical, behavioral and health sciences.

An error was also made in the fifth paragraph of this Announcement that is completed on page 13. Please delete the last sentence of that paragraph. The correct paragraph should read as follows:

Applications to the Alexander von Humboldt Foundation and the Visiting Scientists Program for the National Science Council, Taiwan are available and are accepted throughout the year. All other applications must be submitted by June 1, 1985. **Please note that this is a change in the receipt date for applications to these fellowship programs.**

TO ALL PERSONS INTERESTED IN THE MANAGEMENT OF
NRSA TRAINING PROGRAMS

P.T. 44, 22; K.W. 0720005, 1014002

In the January 4, 1985 edition of the NIH Guide for Grants and Contracts, Vol. 14, No. 1, an error was made in the first sentence of the first paragraph. The correct first sentence should read as follows:

The ten year period 1970-71 to 1980-81 saw a rising graduate school tuition of 9.3 percent in private and 8 percent in public institutions per year as derived from a sample of 17 private and 3 public institutions.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-RR-02

RESEARCH CENTERS IN MINORITY INSTITUTIONS

P.T. 34, 14, 18, FF; K.W. 0780010, 1014001

DIVISION OF RESEARCH RESOURCES

NATIONAL INSTITUTES OF HEALTH

Application Receipt Date: April 15, 1985

The National Institutes of Health (NIH) recently announced a new type of grant, the Research Centers in Minority Institutions (RCMI) Award. Its purpose is "to establish research centers in those predominantly minority institutions which offer doctoral degrees in the health professions or the sciences related to health "... (Report of the House/Senate Conferees on the Fiscal Year 1985 Appropriation for the Office of the Director, NIH).

The RCMI Program will be managed by the Office of the Director, Division of Research Resources (DRR). The program is designed to provide grants of up to \$1,000,000 per year, for five years, to help eligible institutions enrich their research environments via selected improvements in their human and physical resources.

To be eligible to compete for an RCMI Award, an institution must have 50 percent or more minority enrollment and offer doctoral degrees in the health professions or the sciences related to health.

Eligible applicants have been identified through a search of NIH records and institutional inquiries. Officials of eligible institutions will receive copies of the final RFA, program guidelines and supplementary applications directly from the DRR.

Inquiries about this program should be directed to:

Chief, RCMI Program
Division of Research Resources
National Institutes of Health
Building 31 - Room 5B03
9000 Rockville Pike
Bethesda, Maryland 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-EY-01

INSTRUMENTATION, ALTERATION AND RENOVATION, AND CONSTRUCTION

P.T. 02, 18; K.W. 0780010, 0735015, 1014001

NATIONAL EYE INSTITUTE

Application Receipt Date: May 15, 1985

BACKGROUND

The National Eye Institute (NEI) previously announced the availability of a Request for Applications (RFA) for a program that will support grants in three different areas:

1. Acquisition of Specialized Laboratory Instrumentation
2. Alteration and Renovation of Existing Facilities
3. New Construction

\$3,300,000 was appropriated for a Vision Research Facilities Program in Fiscal Year 1985. The full text of the previous announcement may be found in the NIH Guide for Grants and Contracts Vol. 14, No. 1, January 4, 1985.

The RFA program guidelines and applications are now available from the staff contacts listed at the end of this announcement and are being mailed directly to individuals who responded to the preliminary announcement. There are no changes in the program as previously announced except that the NEI share for construction will be limited to 50% and guidelines have been finalized for the maximum to be requested for such type of award.

APPLICATION PROCEDURE

Prospective applicants are strongly encouraged to contact staff of the NEI before any application procedures are initiated to discuss the feasibility of the proposal. Each of the support mechanisms for construction, renovation, and instrumentation must be applied for separately.

This program is described in the Catalog of Federal Domestic Assistance. Eye Research Construction Grants are listed at CFDA No. 13.985. Construction grants made under this program are subject to Executive Order 12372. Awards in support of alteration and renovations or specialized instrumentation are not subject to Executive Order 12372. All awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended, 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 54.

Application forms and detailed program assistance may be obtained from either of the following individuals:

Ronald G. Geller, Ph.D.
Associate Director for Extramural
and Collaborative Programs
National Eye Institute
Building 31 - Room 6A03A
Bethesda, Maryland 20205

Telephone: (301) 496-4903

or

Geoffrey E. Grant, Chief
Extramural Services Branch
National Eye Institute
Building 31 - Room 6A50
Bethesda, Maryland 20205

Telephone: (301) 496-5884

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-EY-02

PROFILE OF VISUAL FUNCTION IN LOW VISION PATIENTS

P.T. 34; K.W. 1002046, 0735015, 0740065, 0415000, 0730000

NATIONAL EYE INSTITUTE

NATIONAL INSTITUTE ON AGING

Application Receipt Date: June 14, 1985
Letter of Intent Receipt Date: May 1, 1985

The National Eye Institute (NEI), in cooperation with the National Institute on Aging (NIA), announces the availability of a Request for Applications for research project grants for support of studies on functional vision in low vision patients. The major objective of this RFA is to encourage scientists and clinicians to relate information derived from laboratory tests of visual function to patients' ability to perform common visually based tasks in their everyday lives. The goal is to develop a battery of tests that could be used by practicing eye care specialists to generate a profile of visual function for each of their patients and then predict how their functioning will improve with the use of specific visual aids.

Surveys of visually impaired persons reveal two main clusters of tasks that present special difficulties for patients' adaptation to limited vision: orientation and mobility tasks and tasks involving visual information extraction. It is expected that multidisciplinary teams of eye care specialists, vision scientists, orientation and mobility specialists, and rehabilitation professionals will be required to address these problems.

This program is described in the Catalog of Federal Domestic Assistance No. 13.871, Strabismus, Amblyopia and Visual Processing. Awards will be made under the authority of the Public Health Service Act, Title III Section 301, (Public Law 78-410, as amended; 42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The mechanism of support for this program will be the traditional individual research project grant (R01). Review of applications for scientific and technical merit will be by an initial review group convened solely for this purpose by the Review and Special Projects Office, NEI. Following the initial review for scientific merit, applications will be reviewed by the National Advisory Eye Council.

Requests for copies of the complete RFA should be addressed to:

Constance W. Atwell, Ph.D.
Chief, Strabismus, Amblyopia, and
Visual Processing Branch
National Eye Institute
Building 31 - Room 6A49
Bethesda, Maryland 20205

Telephone: (301) 496-5301

ANNOUNCEMENT

RESEARCH ON THE CAUSE AND PREVENTION OF MYOPIA

P.T. 34; K.W. 0715100, 0745055, 0755030, 0785055, 0755015

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) encourages the submission of research grant and fellowship applications on the cause, prevention, and methods to retard the progression of myopia. It has been estimated that as many as 25 percent of all Americans between the ages of 12 and 54 are myopic. Myopia seems to occur more frequently among females than among males, more often in whites than in blacks, and to be correlated positively with income and educational level. All forms of myopia cause deficits in distance vision, thereby impairing a person's ability to perform many tasks. However, some persons are afflicted by a more serious, progressive form of myopia that may lead to retina detachment and blindness.

In spite of the widespread occurrence of myopia, little is known regarding its causative factors or whether its development can be prevented or altered. It is known that myopia develops in some species of animals when they are raised in a cage or when their visual fields are restricted. This may occur because the animals' visual experience is limited largely to nearby objects, but this assumption has not yet been proven. Lid suture in some animal models also leads to myopia, presumably by eliminating pattern vision to the closed eye. However, not all species of animals react to lid suture by becoming myopic, and there are many unknown aspects regarding how, why, or when myopia may be induced in susceptible animals via this approach. Lid suture-induced myopia in some animal models may be reversible, but the basis for this reversibility and whether it could provide any clues for reversing human myopia are not known.

Some investigators are pursuing the possibility that the accommodative efforts which accompany close reading or work may be important in the development of myopia. Well-designed studies also are needed to determine whether periodic rest of the eyes from close work or eye exercise might prevent or retard myopia, as has been thought by some individuals and in some cultures. Attempts to prevent or minimize the development of myopia via various types of corrective lenses or medications have produced mixed results.

Because of the inconclusive status of the projects described above, research on the cause, mechanisms and prevention of myopia requires additional emphasis. Listed below are some areas that appear to warrant increased research activity:

This program is described in the Catalog of Federal Domestic Assistance No. 13.871, Strabismus, Amblyopia and Visual Processing. Awards will be made under the authority of the Public Health Service Act, Title III Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS Grants Policies and Federal regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

- o Etiology and mechanisms of myopia in animal models and humans.
- o Determination of whether ocular accommodation affects the development and/or progression of myopia.
- o Epidemiological studies of risk factors for myopia.
- o Clinical trials of treatments thought to prevent or retard the progression of myopia.

Chapter 11 of Vision Research, A National Plan: 1983-1987, Volume Two/Part Five (Report of the Strabismus, Amblyopia, and Visual Processing Panel) provides more information about research needs and opportunities in Optics and Refractive Errors, Including Myopia. Copies of these volumes can be obtained by writing to:

Mr. Julian Morris
Associate Director for Program Planning
and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

I. MECHANISM OF SUPPORT

The mechanism of support for this program will be the Small Grant (R03), Research Project Grant (R01), and New Investigator Research Award (R23). Individual postdoctoral fellowship (F32) and senior fellowship (F33) applications may also be submitted. Program directors are encouraged to use positions on training grants (T32) for training appropriate to research on the cause and prevention of myopia.

II. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates, as indicated below:

Type of Application	Receipt Date	Earliest Possible Funding Date
Research Project Grant (R01) & New Investigator Research Award (R23)	March 1	December 1
	July 1	March 1
	November 1	July 1
Small Grant (R03)	February 1	July 1
Fellowship (F32, F33)	February 1	August 1
	June 1	December 1
	October 1	April 1

This announcement will be effective for two years following the initial receipt date of June-July 1, 1985.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. The review criteria customarily employed by the NIH for regular grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council. It is likely that most applications Research grant applications should be submitted on form PHS 398 (revised 5/82) and fellowship applications on form PHS 416 which are available in the business or grants and contracts offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the application and enter the title **"Research On The Cause and Prevention Of Myopia"**. The original and six (6) copies of the application should be directed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Inquiries should be directed to:

Constance W. Atwell, Ph.D.
Strabismus, Amblyopia, and
Visual Processing Program
National Eye Institute
Building 31 - Room 6A49
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5301

ANNOUNCEMENT

AVAILABILITY FOR REQUEST FOR APPLICATIONS: RFA

85-HD-04

P.T. 34; K.W. 0750020, 1003006, 1003012, 0710100, 0413002, 0760035, 0755025

DESIGN, SYNTHESIS AND TESTING OF NON-STEROIDAL MALE CONTRACEPTIVE AGENTS

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Letter of Intent Receipt Date: April 1, 1985

Application Receipt Date: June 14, 1985

I. BACKGROUND

The Contraceptive Development Branch (CDB) of the Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD), is inviting research grant applications for investigations into the design and synthesis (as well as relevant biological evaluation) of novel non-steroidal male contraceptive agents. By issuing a Request for Applications (RFA), CPR is indicating its intention to encourage investigator interest in this specific research area.

II. RESEARCH GOALS AND SCOPE

One purpose of this RFA is to encourage a joint venture of synthetic chemists and reproductive biologists into conducting investigations involving the design of novel non-steroidal agents for fertility control in the male and the testing of their hypotheses by synthesis and biological evaluation. If, however, the synthetic chemist cannot secure the necessary biological testing commitment, he/she may request the CDB to test the compounds in appropriate, standard assays.

In considering and designing relevant chemical agents it is necessary to recognize that the pharmacological regulation of fertility is unique in that one is not dealing with a specific disease entity and that the risk to benefit ratio and the side effects must be much lower than those ordinarily accepted in the therapeutic treatment

This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

of pathological conditions. In recognition of this approach, it is justifiable to exclude all agents which have the potential for toxic manifestations, e.g., alkylating agents, nonspecific anti-metabolites, antimitotic agents, etc.

The CDB is currently supporting several projects involving the synthesis of LHRH analogs and does not wish to encourage further work in this area under this RFA. For similar reasons the CDB is not soliciting applications for the synthesis of steroids for male fertility regulation. The CDB has also concluded that further synthesis of gossypol analogs is not warranted at this time in view of the lack of in vivo activity (at the doses tested) seen with all of the gossypol analogs synthesized to date.

The research areas for which applications are sought with this RFA are:

- A. Design and synthesis of inhibitors of testicular sperm development.
- B. Design and synthesis of post-testicular inhibitors of sperm maturation and function.
- C. Design and synthesis of agents with preferential effects on Sertoli cells.

III. STAFF CONTACT

For further information and a copy of the RFA, contact:

Marvin J. Karten, Ph.D.
Contraceptive Development Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - Room 7A04
National Institutes of Health
Bethesda, Maryland 20205

Telephone: 301/496-1661

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HD-05

BIOEFFECTS OF ULTRASOUND

P.T. 34; K.W. 0607024, 0411005, 0710030, 0775020, 0785055, 0775025

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: July 15, 1985

The Genetics and Teratology Branch (GT) of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) invites research project grant applications (R01s) for studies of the bioeffects of ultrasound on developing organisms.

I. BACKGROUND INFORMATION

The use of ultrasound in the management of pregnancies has since its introduction into obstetric practice in the 1950's become a highly sophisticated technology that is capable of detecting many structural and functional abnormalities of the developing fetus. It may be employed to determine fetal size and gestational age, assess fetal structural anomalies, detect multiple and ectopic pregnancy, and as a guide in fetal therapy. The technology has overcome the many limitations of roentgenology and has virtually eliminated the need for fetal exposure to ionizing radiation.

Because of these advantages, the use of diagnostic ultrasound has grown rapidly until today about one-third to one-half of all pregnant women, and therefore at least one million developing fetuses, are exposed to ultrasound radiation in the United States each year. Yet it is not clear if diagnostic ultrasound usage during pregnancy is free of risk to the developing fetus. There have been no reports of clinically observed adverse effects associated with the prenatal use of ultrasound, but clinical impressions, although valuable, do not establish conclusively that the use of ultrasound involves no risks. Past epidemiological studies have not yielded conclusive evidence regarding safety or adverse effects of ultrasound because of inadequate study design. Animal and cellular studies have also been unable to rule out or suggest harmful ultrasound effects and some studies could not be repeated. Furthermore, information on exposure conditions of previous ultrasound bioeffects studies is frequently incomplete.

This program is described in the Catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The extraordinary acceptance of ultrasonography as an indispensable prenatal diagnostic tool that might soon result in prenatal exposure of a majority of infants to ultrasound in utero, as well as the lack of the necessary bioeffects information, lead NICHD to encourage ultrasound research. A better data base for reasonable estimates of bioeffects and risks of ultrasound on developing organisms should result in the near future.

II. RESEARCH GOALS AND SCOPE

This RFA solicits applications from qualified investigators for interdisciplinary studies to advance our understanding of potential bioeffects of ultrasound that might be initiated in developing organisms before birth. Investigations should search for ultrasound effects covering the organisms' earliest developmental periods and on through embryogenesis, fetal and postnatal stages to maturity. Studies may include potential defects, whether they are immediate or delayed, at all levels of biological organization to determine possible molecular, cellular, as well as tissue and organ-level key developmental processes that might be affected. This should include examination of differential gene action, of all cellular morphogenetic processes, and of determination and differentiation that specify the organisms' maturation. Investigations may utilize appropriate animal models for ultrasound effect determinations and/or cell, tissue, organ or embryo culture methods to carry out such studies. Epidemiological studies are also encouraged to exclude major ultrasound effects, to examine for subtle ultrasound effects, and to determine frequencies of potential lasting effects, should some be discovered. Clinical investigations are sought that contribute to improved prenatal use of the ultrasound technology, but efficacy of such studies is not an objective of this RFA. Investigations of fundamental ultrasound interaction mechanisms with developing biological systems and separation of different causes of potential adverse developmental outcomes as well as of appropriate ultrasound dosimetry are also encouraged.

III. STAFF CONTACT

For further information, and a copy of the RFA Contact:

Anne K. Krey
or
Delbert H. Dayton, M.D.
Genetics and Teratology Branch
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building - Room 7C09
Bethesda, Maryland 20205

Telephone: (301) 496-496-5541

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

85-HD-06

COOPERATIVE MULTICENTER NETWORK OF NEONATAL INTENSIVE CARE UNIT
(NICUs)

P.T. 34; K.W. 0755015, 0403020, 0745020, 0415000, 0715155

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receive Date: June 14, 1985

The National Institute of Child Health and Human Development (NICHD) invites applications from investigators willing to participate with the NICHD under a Cooperative Agreement in a multicenter cooperative clinical study designed to investigate the safety and efficacy of new treatment and management strategies that may be employed in the care of infants in NICUs. The Institute program staff will collaborate with the principal investigators of the selected NICUs in identifying research topics of high priority and in designing protocols appropriate to the evaluation of optimum management in the care of infants admitted to NICUs. It is anticipated that the program will consist of four phases:

- Phase 1. (2 months) Identification of issues of importance in clinical care of sick newborns and prioritization of those issues relative to patient need.
- Phase 2. (6 months) Design of diagnostic and treatment protocols and data sets to be accepted by all participating organizations.
- Phase 3. (52 months) Institution of management protocols, data collection, and data transfer.
- Phase 4. (40) months) Initiation of prospective planning pertaining to termination of studies, addition of new protocols, and delineation of future research needs. This phase will begin six months after Phase 3 has started.

This program is described in the Catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MECHANISM OF SUPPORT

The funding mechanism to be used to assist the scientific community in undertaking this system of clinical investigation will be a Cooperative Agreement between the participating units and NICHD. The major difference between a Cooperative Agreement and a research grant is that there will be substantial programmatic involvement of NICHD staff above and beyond the levels required for traditional program management of grants.

APPLICATION PROCEDURE

Applications must be submitted on form NIH 298 (Revised 5/82) which includes form HHS 596 dealing with protection of human subjects.

ADDITIONAL INFORMATION

Potential applicants are encouraged to request a detailed request for application by telephoning:

Charlotte S. Catz, M.D.
Chief, Pregnancy and Perinatology Branch
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building - Room 7C09
Bethesda, Maryland 20205

Telephone: (301) 496-5575

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

85-HD-07

COOPERATIVE MULTICENTER NETWORK OF MATERNAL-FETAL MEDICINE UNITS (MFMUs)

P.T. 34; K.W. 0785135, 0745055, 0755015, 0730005, 0745020, 0415000

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: June 14, 1985

The National Institute of Child Health and Human Development (NICHD) invites applications from investigators willing to participate with the NICHD under a Cooperative Agreement in a multicenter cooperative clinical study designed to investigate problems in clinical obstetrics, particularly those related to prevention of low birth weight. The Institute program staff will cooperate with the principal investigators of the selected maternal-fetal medicine units (MFMUs) in identifying research topics of high priority and in designing protocols appropriate to the evaluation of optimum management in these high priority areas. It is anticipated that the program will consist of four phases (duration of phases is estimated only):

- Phase 1. (2 months) Identification of issues of importance in clinical obstetrics, and prioritization of those issues relative to patient need.
- Phase 2. (6 months) Design of diagnostic and treatment protocols and data sets to be accepted by all participating organizations.
- Phase 3. (52 months) Institution of clinical trial protocols, data collection, and data transfer.
- Phase 4. (40 months) Initiation of prospective planning pertaining to termination of studies, addition of new protocols, and delineation of future research needs. This phase will begin six months after Phase 3 has started.

It is anticipated that approximately six to eight clinical centers will be involved in the program. The deadline for receipt of applications is June 14, 1985. Applications received after this date will not be considered. Only institutions in the United States will be eligible for participation.

This program is described in the Catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MECHANISM OF SUPPORT

The funding mechanism to be used to assist the scientific community in undertaking this system of clinical investigation will be a Cooperative Agreement between the participating units and NICHD. The major difference between a Cooperative Agreement and a research grant is that there will be substantial programmatic involvement of NICHD staff above and beyond the levels required for traditional program management of grants.

APPLICATION PROCEDURE

Applications must be submitted on form NIH 398 (Revised 5/82) which includes form HHS 596 dealing with protection of human subjects.

ADDITIONAL INFORMATION

Potential applicants are encouraged to request a detailed Request for Applications by telephoning:

Donald McNellis, M.D.
Pregnancy and Perinatology Branch
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building, Room 7C09
Bethesda, Maryland 20205

Telephone: (301) 496-5575

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HD-08

INJURY AND INJURY PREVENTION IN CHILDREN

P.T. 34; K.W. 0770005, 0715005, 0715210, 0745055, 0715020, 0715175, 0725000, 0502017

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Letter of Intent Receipt Date: May 15, 1985
Application Receipt Date: July 15, 1985

I. BACKGROUND

The Human Learning and Behavior Branch (HLB), Center for Research for Mothers (NICHD) supports research in behavioral pediatrics, a new research area which focuses on applying principles of human learning to health and illness behaviors of children, as well as the behaviors of adults significant in affecting the child's health environment. A part of this research effort seeks to determine the role of behavioral factors in the etiology of childhood injuries and their prevention. In the United States, injuries have replaced infectious diseases as the leading cause of death and disability among children and young adults. Because the NICHD is the appropriate agency to deal with such public health issues and also recognizes the magnitude of the problem, research on injuries is a major priority for the Institute.

This RFA invites scientists to submit grant applications for research concerned with the prevention of injury in children. The focus should be directed to unintentional injury or trauma. In agreement with the American Academy of Pediatrics, the NICHD uses the specific term "injury" or "trauma" in place of the more general term "accident."

II. OBJECTIVE AND SCOPE

This RFA invites scientists to submit grant applications for research on childhood injuries and injury prevention. Applicants should seek to clarify the major

This program is described in the Catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Title III Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.



behavioral and environmental variables responsible for specific kinds of childhood injuries. Of particular interest are studies that identify and measure observable behaviors of parents and children that are precursors of injury occurrence or injury avoidance (safety); that is, behaviors closely linked to injury morbidity and mortality data. Also relevant are observational studies of environmental conditions modifiable by parents or children which lead to injury or injury reduction. Research needs include the development of experimental models that explain (in analogue situations) the origins and continuation of both risk-taking and injury avoidance (safety) behaviors. Findings from such research studies can provide a basis for developing effective interventions.

Of particular interest are studies that develop generic intervention strategies that can reduce identified antecedent behaviors and/or environmental factors that increase the likelihood of injury. For example, to reduce the number of poison related fatalities and injuries in children, one strategy would encourage parents to use tamper-resistant caps on medications and other toxic substances, and also remove lead based paint from all indoor surfaces. This passive type strategy has proven more successful in reducing childhood poison fatalities than the active approach of continually monitoring the child's activities.

Also relevant are studies to: (a) determine the most effective educational training procedures for differing populations of concern (e.g., children of different ages and sex), (b) identify societal variables that affect accident behavior, and (c) categorize children's responses to accidents, covering both dangerous and safe behaviors, thereby facilitating the development of a single intervention approach that serves multiple kinds of accident behavior.

III. STAFF CONTACT

For further information and a copy of the RFA, contact:

Josephine D. Arasteh, Ph.D.
Health Scientist Administrator
Human Learning and Behavior Branch
Center for Research for Mothers
and Children
National Institute of Child Health
and Human Development

Telephone: (301) 496-6591

NIH Guide for Grants and Contracts

Vol. 14, No. 4, March 29, 1985

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National Institutes of Health

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

NOTICE

NIH PEER REVIEW APPEALS SYSTEM

P.T. 34; K.W. 1014002

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) has initiated an appeals process whereby applicants may request an examination of their concerns about the referral and peer review of their applications for grants and cooperative agreements (assistance awards).

This process is intended to resolve those concerns which arise from perceived shortcomings or errors in the substance or procedure of peer review--i.e., from receipt and assignment of an application through its review by the National Advisory Council or Board (subsequently abbreviated to "advisory council"). Such concerns may involve NIH's refusal to accept an application; a disputed assignment of the application to an initial review group or to an NIH Bureau, Institute, or Division (subsequently abbreviated to "Institute"); perceived insufficient expertise on the initial review group or site visit team or conflict of interest on the part of one or more of its members; apparent factual or scientific errors, oversights, or bias associated with the review of an application at the initial or advisory council review; and possibly inappropriate handling of the review or of the application.

On the other hand, the appeals process is not intended to resolve purely scientific disputes between peer reviewers and the investigator; to provide a mechanism for allowing investigators to submit information that should have been presented in the original proposal; or to provide a forum for disputing priority score determinations in the absence of specific and substantive evidence pointing to a flawed review.

The appeals process will not supersede or bypass the peer review process, but if serious shortcomings are found to have occurred in the review of an application, they will be rectified by one of the following actions: rereview by the same or another initial review group; special consideration by the advisory council; or administrative action authorized by the Institute Director or staff.

NIH encourages investigators to discuss their concerns with the appropriate NIH staff before requesting an examination of these concerns under the appeals process. When requesting such an examination, principal investigators should clearly describe their concerns and support their position by pertinent facts and reasons.

Under the appeals process, all concerns must first be directed to the NIH component which at the time is responsible for the application.^{1/} Appropriate officials will

^{1/} The Division of Research Grants (DRG) is responsible for all matters relating to the assignment and initial review of applications by DRG study sections until the review has been completed. The awarding Institute is responsible for all matters relating to the review of applications by initial review committees in the Institute and for all matters after the initial review has been completed.

thoroughly examine the investigator's concerns, frequently with the help of the initial reviewers or other experts, and, if shortcomings are found to have occurred, every effort will be made to rectify them in a timely manner.

If the principal investigator seriously disagrees with the resolution of his/her concerns by the responsible NIH component, the investigator and applicant organization may jointly appeal to the Office of Extramural Research and Training, which is a component of the Office of the Director, NIH. The appeal must clearly set forth the original dispute and the reasons for disagreeing with the resulting decision. To allow for a complete and independent examination of the appeal--which will frequently entail consultation with scientific or other experts--the application will be withdrawn from the regular review process until the appeal is resolved. An amended application submitted during consideration of the appeal will inactivate the original application and the accompanying appeal. The NIH Deputy Director for Extramural Research and Training and the Institute Director in charge of the application will render the final NIH decision on the appeal and communicate it to the applicant.

How to Use the Appeals System:

Communications before the Initial Review

After being notified about the assignment of an application to the initial review group and the awarding Bureau, Institute, or Division, the principal investigator may direct his/her serious concerns about the assignment of the application to the Deputy Chief for Referral, Referral and Review Branch, DRG, Westwood Building, Room 248, National Institutes of Health, Bethesda, Maryland 20205, and about the pending review of the application to the executive secretary of the initial review group.

Communications after the Initial Review

After having received the summary statement, the principal investigator may direct his/her serious concerns about the review, including advisory council review, to the responsible institute staff. For competing applications, this is usually the program official listed on the Notice of Grant Award. If this person is unknown, investigators should write their concerns directly to the Office of the Associate Director for Extramural Programs in the awarding organization,^{2/} NIH, Bethesda, Maryland 20205.

All Appeals

After having received the definitive response from the responsible NIH awarding organization--and the principal investigator seriously disagrees with the decision--he/she and the applicant organization may appeal to the Appeals Officer, James A. Shannon Building, Room 213, NIH, Bethesda, Maryland 20205, (301) 496-5358.

^{2/} The name of the awarding organization may be determined from the grant identification number; i.e., AG-National Institute on Aging, AI-National Institute of Allergy and Infectious Diseases, AM-National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, CA-National Cancer Institute, DE-National Institute of Dental Research, ES-National Institute of Environmental Health Sciences, EY-National Eye Institute, GM-National Institute of General Medical Sciences, HD-National Institute of Child Health and Human Development, HL-National Heart, Lung, and Blood Institute, LM-National Library of Medicine, NS-National Institute of Neurological and Communicative Disorders, RR-Division of Research Resources.

NOTICE

AVAILABILITY OF FROZEN SERUM PANELS

P.T. 36,34; K.W. 0755010, 0780005, 0750010, 0760025, 0760060, 0760070

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) is interested in evaluating serum assays that are potentially useful in the diagnosis of cancer. A variety of serum components (e.g., peptide hormones, viral antigens, isoenzymes, glycoproteins, antibodies, immune complexes, tumor-associated antigens, carbohydrates, phospholipids, nucleosides, etc.) have been reported to be useful in cancer diagnosis and/or in monitoring cancer treatment or recurrence. Coded panels composed of 1 ml aliquots of pretreatment frozen sera from patients with various neoplasms, from benign disease patients, and from healthy controls are available to investigators to evaluate assays in which preliminary results indicate the ability to discriminate between cancer patients and controls. Promising results may form the basis for a subsequent grant application. Preliminary data documenting a useful test must be submitted and should include: a brief description of the assay, results in patients with cancer, results in patients with non-malignant disease, results in healthy control subjects and reprints of published work, if available. Request for a coded serum panel should be sent to:

Diagnosis Serum Panels
Project Officer NCI-Serum Bank
Diagnosis Branch
National Cancer Institute
National Institutes of Health
Westwood Building - Room 10A10
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNOUNCEMENT

ADDITIONAL INFORMATION REGARDING RFA 85-DE-01 - (OROFACIAL PAIN RESEARCH CENTERS)*

P.T. 04; K.W. 0715150, 0785040, 0710100, 0785035, 0785055, 0705055, 0755030, 0414011

NATIONAL INSTITUTE OF DENTAL RESEARCH

The National Institute of Dental Research (NIDR) wishes to inform potential applicants for this Center program that funding for meritorious applications responsive to this RFA may not occur until FY 87.

Nevertheless, the NIDR recognizes the urgency of stimulating research in this scientific area, and thus is retaining a receipt date of June 15, 1985, with review to follow on a schedule to be announced to applicants.

Applicants with further questions should contact:

Patricia S. Bryant, Ph.D.
Health Scientist Administrator
Craniofacial Anomalies, Pain Control
and Behavioral Research Branch
National Institute of Dental Research
Westwood Building - Room 506
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: 301 - 496-7807

* Originally announced in the January 4, 1985, NIH Guide for Grants and Contracts.

ANNOUNCEMENT

MOLECULAR BIOLOGICAL AND GENETIC BASIS OF AGING

P.T. 22, 34, 44; K.W. 0710010, 1002004, 1002008, 1002019, 0765015, 0790010, 0760015, 0765020, 0760070

NATIONAL INSTITUTE ON AGING

I. INTRODUCTION

The National Institute on Aging (NIA) was established in 1974, to conduct and support biomedical, behavioral, and social research and training related to the aging process and the diseases and other special problems and needs of the aged. Consistent with this mandate, Molecular Biology and Genetics, subprograms of the Molecular and Cellular Biology Program, support research on the molecular and genetic mechanisms of aging. The purpose of this announcement is to encourage further research and training activities using modern tools of molecular biology and genetics to elucidate the molecular bases of aging processes.

II. BACKGROUND

Recent advances in the ability to isolate and amplify specific pieces of DNA, to alter DNA at specific sites, and to move DNA sequences to new locations in the genome, are providing insights into the structure of genes and the regulation of their expression. The broad outlines of genetic organization are now becoming clear, and the ability to alter these sequences and relate structure to function in both a gene and its gene product can lead to an understanding of how genes function. Although several genetic diseases have been identified (e.g. Werner's Syndrome, Down's Syndrome, Huntington's Disease) that appear to accelerate certain features of aging, the genetic basis of aging is poorly understood. The recent identification of a DNA fragment carrying the gene for Huntington's Disease suggests that fragments carrying this gene or other genes related to aging processes can be isolated and extensively characterized.

Gene expression can be altered not only by random or specific mutation of control sequences, but also by insertion of transposable elements into the genome in the vicinity of a gene, and by chromosomal rearrangements. Extrachromosomal DNA

This program is described in the Catalog of Federal Domestic Assistance No. 13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. Awards will also be made under the authority of the Public Health Service Act, Section 472, 42 USC 2891-1, and administered under PHS grants policy and Federal Regulations 42 CFR Part 66. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

has now been demonstrated in a variety of eukaryotic organisms, and there is evidence that at least some of the DNA has the properties of transposable elements. Thus it is possible that transposable elements could play a role in the aging process by altering patterns of gene expression.

Considerable evidence has been accumulating to indicate that proteins in old organisms may differ from proteins in young organisms. These differences could arise in a number of ways, including lowered fidelity of transcription or translation, post-translational modification, racemization of amino acids already incorporated into proteins, and expression of genes for isozymes. Although it is probable that one or more of these processes contributes to the heterogeneity of proteins in aging cells, it is not clear whether any of these events is a primary cause of cellular aging.

III. GOALS AND SCOPE

The goal of this announcement is to encourage research on the mechanisms of cellular aging using modern genetic and molecular biological approaches. The new techniques available for the study of gene structure and expression provide an opportunity to elucidate the molecular details of events and gene products involved in aging processes. Such studies could lead to an understanding of mechanisms of age-related diseases and functional decline in various organisms.

IV. SPECIFIC OBJECTIVES

The NIA seeks research and training grant applications to test hypotheses and elucidate mechanisms of aging using genetic and molecular biological approaches in various biological systems. Research is encouraged in, but not limited to, the following areas:

- A. Identify and discern the nature of genes involved in aging processes in a variety of biological systems, and characterize the regulation of expression of these genes and interactions between the products of these genes.
- B. Identify and characterize normal human genes and their products, and the molecular alterations of these genes, which may underlie diseases that appear to accelerate certain features of aging, e.g. Alzheimer's Disease and progeroid syndromes.
- C. Characterize the effect of aging on the molecular mechanisms of replication, repair, transcription, RNA processing, translation, post-translational processing, transport of proteins, and turnover of proteins and messenger RNA. These experiments should focus on important age-related changes in relevant biological systems.
- D. Characterize modifications of the structure and functions of nuclear components which accompany aging.
- E. Characterize modifications of the structure and functions of components of cellular organelles which accompany aging.
- F. Determine the possible roles of extrachromosomal DNA and transposable elements in aging processes.

- G. Characterize factors and processes which regulate DNA replication and cell proliferation, and are altered during aging.
- H. Employ a dynamic systems analysis approach to discover those biochemical events (e.g. gene expression, metabolism, organelle function) which are rate-limiting to, or controlling, a specific clearly-defined aging process.
- I. Develop new model systems amenable to molecular and genetic analysis of aging organisms, using particularly organisms with a short life span.

Although studies with human cells and tissues are preferred, use of invertebrates and other vertebrates may be desirable where shorter lifespans and better genetic systems are an advantage. Therefore, the NIA supports several colonies of animals for use in aging research. Applicants interested in using these animals should contact the following persons:

Animal:	Rats and Mice	Caenorhabditis elegans
Contact person:	Jane Soban	Dr. Donald Riddle, Director
	Molecular and Cellular Biology Branch Building 31 - Rm. 5C19 National Institute on Aging, NIH Bethesda, MD 20205	Caenorhabditis Genetics Center Division of Biological Sciences University of Missouri Columbia, MO 65211
Telephone:	301/496-6402	314 - 462-6363

To support research on cellular aging, the NIA has also established, under contracts, an Aging Cell Repository. Additional information on the Aging Cell Repository may be obtained from the publication by N.K. Das and D.G. Murphy, in Exp. Aging Res. 4:321-331 (1978) available upon request from the Molecular and Cellular Biology Branch, or by calling:

Dr. DeWitt Hazzard
Program Administrator for Cell Biology
Building 31 - Room 5C19
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: 301 - 496-6402

V. MECHANISMS OF RESEARCH AND RESEARCH TRAINING SUPPORT

The primary mechanisms for support of this program are:

1. Research grant
2. Program project grant, involving several projects with a common focus.
3. Postdoctoral fellowship.

Additional mechanisms for support are:

1. New investigator research award for applicants who have not previously been supported as principal investigators by a U.S. Public Health Service research grant; ceiling \$37,500 per year for three years, including salary support up to \$25,000 per year.
2. Physician scientist award for clinically trained investigator; ceiling \$40,000 per year for salary and up to \$20,000 per year for supplies for five years
3. Research career development award; awarded for 5 years with up to \$40,000 per year for salary.
4. Institutional training grant.

Potential applicants should contact NIA staff for information and advice.

VI. REVIEW PROCEDURES AND FUNDING POLICY

According to standard referral guidelines, the NIH Division of Research Grants will assign all applications to appropriate NIH study sections for initial scientific review, and to the appropriate Institute or Division for final review by its National Advisory Council or Board. Applications submitted in response to this program announcement will compete with all NIA grant applications for funding consideration. No set aside money is available for these applications.

VII. METHOD OF APPLYING

Use the appropriate NIH research or research training grant application kits. If your institution does not have them, copies may be obtained by writing:

Office of Grant Inquiries
Division of Research Grants
National Institute of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

Please type the phrase NIA Molecular Biology Program on the face page of the application and enclose a cover letter indicating that the application is in response to this program announcement. Forward the application to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20205

Application deadlines are March 1, July 1, and November 1 for research grant applications, and February 1, June 1, and October 1 for individual or institutional National Research Service Awards, program project grants, physician scientist awards, and research career development awards.

Applicants are strongly encouraged send a letter of intent to the Molecular Biology Program at the following address. Please include the name of the principal investigator, address, title of application, and abstract of the proposed research. A letter of intent is not binding, is not a requirement for consideration, and does not enter into the review of a subsequent application. Letters are requested in order to provide NIH staff with an indication of the number and scope of applications for purposes of planning the review.

Dr. Huber R. Warner, Acting Chief
Molecular and Cellular Biology Branch
Building 31 - Room 5C19
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-6402

ANNOUNCEMENTDOMINANTLY INHERITED POLYCYSTIC KIDNEY DISEASE - MULTIDISCIPLINARY APPROACH

P.T. 34; K.W. 0785095, 07100220, 1002004, 1002008, 1002019, 1003002, 0785055, 0785165

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES AND DIGESTIVE AND KIDNEY DISEASES

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD), of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK), encourages investigator initiated grant applications to study the pathogenesis of Dominantly Inherited Polycystic Kidney Disease (DIPKD). Little is known of the natural history or pathogenesis of DIPKD other than it leads to progressive renal failure. Anatomically DIPKD is a slowly evolving disorder, characterized by a focal, progressive increase in the diameter of some renal tubules which compress the otherwise normal adjacent renal tissue. The two current theories of cyst development in DIPKD are: (a) a primary defect in tubular basement membrane which favors cyst formation and (b) cyst formation due to the obstruction of urine flow caused by the proliferation of epithelial cells leading to partial obstruction of the tubular lumen.

A significant disease process, DIPKD affects 200-400 thousand Americans and invariably leads to progressive renal failure in 9-11% of patients in the End Stage Renal Disease (ESRD) program. It is estimated that the ESRD program, supported by Medicare, approaches \$2.0 billion in annual expenditures; of these costs, approximately \$180-\$200 million goes toward the care of patients with DIPKD. Time lost from work and time contributed by family members escalate the figure higher. DIPKD does not become clinically apparent until the 3rd-5th decade of life, a time after which the opportunity for genetic transmission has occurred.

Because of the lack of autosomal dominant animal models of polycystic kidney disease, drug-induced models have frequently been used. A polycystic lesion has been induced in rats and mice using diphenylamine, 2-amino-4, 5-diphenylthiazide, nordihydroguariaretic acid and cis-diamine dichloroplatinum. The renal diseases induced by each of these have been well characterized with respect to evolution of renal failure and morphological changes. Spontaneous forms of polycystic kidney disease has been detected in two mouse strains and recently an antelope population was identified in Florida that has spontaneous polycystic kidney disease.

This program is described in the Catalog of Federal Domestic Assistance No. 13.849, Kidney, Urologic, and Hematologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Specific objectives of this solicitation are to: (1) encourage increased research activity in the DIPKD area; (2) develop both Data and Cell Banks of the largest known polycystic disease families that will be available to the research community, and (3) encourage the submission of research grant applications that will carry out studies aimed at discovering the primary defect through molecular analysis or at finding the affected locus or loci through linkage analysis in large families.

The interdisciplinary nature of these studies will require collaboration among experts in areas such as the major disciplines of genetics, molecular/cellular biology, biochemistry, renal physiology and pathophysiology, nephrology, pathology, and epidemiology.

Since the bulk of the data relating to the pathogenesis of DIPKD has been obtained in experimental models, its relevance to human disease cannot be assessed without similar data from human subjects. In terms of potential for carrying out human studies, two to three centers in the United States and another in Denmark are known to have identified large DIPKD patient populations, which provide unique resources for studies that should advance our understanding of the pathogenesis of the disease. Furthermore, based on the success in recent years of developing genetic markers for other heritable diseases, such as Huntington's Disease, linkage studies in these families could lead to the identification of the chromosome which carries the gene responsible for the disorder. Once identified and cloned, the gene product could prove useful in the early detection of gene carriers.

The award of grants pursuant to this program announcement is contingent upon receipt of appropriated funds for this purpose. Although this solicitation is included in the NIADDK funding plan for Fiscal Year 1986, support is contingent upon receipt of funds for this purpose. The specific amount to be funded will depend upon the merit of the applications and funding is expected to begin April 1986.

All PHS and NIH grant policies governing regular research project grants, including cost sharing, apply to applications received in response to this program announcement.

I. REVIEW PROCEDURES AND CRITERIA

A. Assignment of Application

Applications will be received by the National Institutes of Health (NIH), Division of Research Grants (DRG), referred to an appropriate Study Section for scientific merit review, and assigned to NIADDK for possible funding, unless programmatic considerations indicate more appropriate assignment to another institute. These decisions will be governed by normal DRG Referral Guidelines.

B. Review Procedures

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research grant applications, and in accord with the usual NIH peer review procedures. Applications will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (Study Section), and then by the National Advisory Council of the NIADDK or other appropriate institute. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

II. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions or from the DRG, NIH. The phrase **"PREPARED IN RESPONSE TO NIADDK KIDNEY PROGRAM ANNOUNCEMENT - DOMINANTLY INHERITED POLYCYSTIC KIDNEY DISEASE"** should be typed in space #2 on the first page of the application.

III. APPLICATION RECEIPT DATES

Applications will be accepted in accordance with the usual NIH receipt dates for new applications. Deadline dates are: July 1, November 1, March 1.

The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact the following individual:

M.J. Scherbenske, Ph.D.
Renal Physiology/Pathophysiology
Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
Westwood Building - Room 621
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7458

ANNOUNCEMENT

TRANSFUSION MEDICINE ACADEMIC AWARD

P.T. 34; K.W. 0750010, 0785035, 0502000, 0720005

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: October 15, 1985

The Transfusion Medicine Academic Award (TMAA) was initiated in January 1983, to (1) encourage the development of curricula in transfusion medicine, and (2) allow the awardee to broaden his or her expertise in transfusion medicine so as to contribute more effectively to the teaching, research, and clinical needs of this discipline. The term "transfusion medicine" is used to define a multidisciplinary area concerned with the proper use or removal of blood and its components in the treatment or prevention of disease states (other than in renal hemodialysis). Schools of medicine, osteopathy, or veterinary medicine (United States or its possessions and territories) singly or in concert one with another, are eligible to apply for one 5-year TMAA (nonrenewable), providing they possess the requisite blood bank, patient care, and research facilities required for such an activity. The TMAA may provide salary, fringe benefits, supporting costs, and indirect costs to well-trained investigator-faculty members who are skilled organizers and negotiators. The number of awards made each year will depend on the availability of funds.

The Division initiated the TMAA program to encourage the development of teaching programs in transfusion medicine. At present, teaching, research, and clinical responsibilities in transfusion medicine are rarely coordinated into a definable program but are dispersed among basic and clinical science disciplines and among activities of the local transfusion services or blood center facility. It is important to note that establishing a transfusion medicine curriculum may not require additional curriculum; existing teaching materials (components of other disciplines) may be coordinated into an overall program and organized to focus on emerging and important areas of transfusion medicine. Some schools may find it desirable to assemble the appropriate components into a specific unit. Others may wish to retain the transfusion medicine disciplines as part of another major department.

This award is also intended to:

- o Attract to the field of transfusion medicine outstanding students and promising young clinicians and scientists who can serve the teaching, research, and clinical aspects of transfusion medicine.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.839, Blood Diseases and Resources. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.



- o Encourage the development of faculty capable of providing appropriate instruction in the field of transfusion medicine.
- o Facilitate interchange of information, and evaluation and educational techniques among research, medical, and blood service communities.
- o Enable the grantee institution to develop a continuing transfusion medicine program, using local support when this award terminates.

Requests for the TMAA program guidelines should be directed to:

Fann Harding, Ph.D.
National Heart, Lung, and Blood Institute
Federal Building, Room 5A08
Bethesda, Maryland 20205

Telephone: (301) 496-1817

NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 14, No. 5, April 26, 1985

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

NATIONAL CANCER INSTITUTE SHORT TERM RESEARCH EXPERIENCE
FOR STUDENTS IN HEALTH PROFESSIONAL SCHOOLS

P.T. 34, 40; K.W. 0710030, 0720005

NATIONAL CANCER INSTITUTE

This is a reminder that the National Cancer Institute (NCI) supports short-term research experiences for students of medical and dental schools through the R25 Cancer Education Program Grants. Also, please note that a R25 applicant need not engage in the curriculum development activity described in past R25 guidelines in order to apply for support short-term research experiences for health professional students or prebaccalaureate minority students, or for continuing education medical activities. Additional information may be obtained from:

Program Director
Cancer Training Branch, DCPC
National Cancer Institute, NIH
Blair Building - Room 424
Bethesda, Maryland 20205-4200

Telephone: (301) 427-8898

NOTICENIA MORATORIUM ON SMALL RESEARCH GRANT APPLICATIONS

P.T. 34; K.W. 0710010, 0710030

NATIONAL INSTITUTE ON AGING

Effective immediately the National Institute on Aging (NIA) is placing a moratorium on acceptance of Small Research Grant applications (R03). NIA will schedule review and award for small grant applications submitted for the February 1, 1985 deadline within six months of receipt as announced in the NIH Guide for Grants and Contracts Vol. 14, No. 2, February 1, 1985. Should the Institute's priorities permit resumption of expedited review, a new announcement will be published in the Guide.

ANNOUNCEMENT

HYBRIDOMA DATA BANK

P.T. 36; K.W. 0760030, 0780015, 1004008

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The National Institute of Allergy and Infectious Diseases (NIAID) announces the international availability of a new public resource, a computerized registry of data concerning cloned cell lines and their immunoreactive products. Data for the bank are being obtained from the scientific literature, individual investigators, and commercial suppliers of immunoreactive materials. The development of the Hybridoma Data Bank (HDB) was coordinated through the International Council of Scientific Unions' Committee on Data for Science and Technology (CODATA) and the International Union of Immunological Societies (IUIS). Support for the CODATA-IUIS HDB is being provided by the NIAID, National Cancer Institute, National Institute of Dental Research, National Institute of General Medical Sciences, Division of Research Resources, Food and Drug Administration, Department of Agriculture, National Science Foundation, the American Type Culture Collection, the World Health Organization, and by scientific organizations within the governments of Canada, France, Japan, Switzerland and the United Kingdom.

International in scope, three identical copies of the data in the HDB will be housed on mainframe computers at the National Institutes of Health, Japan's Institute for Physical and Chemical Research and at a location in Western Europe currently being developed. At this time, the HDB is actively soliciting data from developers of cell lines and immunoreactive products for inclusion in the bank; its services are now being provided without cost to the scientific community in response to specific inquiries.

For further information, write to:

CODATA-IUIS HYBRIDOMA DATA BANK
American Type Culture Collection
12301 Parklawn Drive
Rockville, Maryland 20852
USA

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HD-09

NON-INVASIVE ASSESSMENT OF THE NORMALITY OF SINGLE PRE-GASTRULA EMBRYOS

P.T. 34; K.W. 0413002, 1002017, 1013039, 1002024, 0755040, 1002059, 1002034, 1007009

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: July 15, 1985

The Reproductive Sciences Branch (RSB), of the Center for Population Research (CPR), of the National Institute of Child Health and Human Development (NICHD), announces the availability of a Request for Applications (RFA), on rapid non-invasive assessments of the normality of single pre-gastrula embryos. The purpose of this program is to provide one or more methods of determining the probability that an individual egg or embryo will undergo normal development, safe transfer and successful implantation after in vitro fertilization and embryo culture. The need for such methods arises from the frequent observations that embryos maintained in vitro are inferior to those raised in vivo and result in a low rate of successful pregnancies.

Examples of the non-invasive assessments that could be useful include: direct observations through microscopic means or other highly sensitive sensors of the activities or properties of living cells; uptake of natural compounds, such as micronutrients measured by depletion of compounds from culture media; release or secretion of compounds from embryos into the medium; degradative enzyme activity measured by digestion of substrates in the medium; transient, non-invasive assays of cell-surface molecules. Although the primary focus of this RFA is upon mammalian eggs and embryos (small laboratory mammals, non-human primates, farm animals, others), RSB also wishes to encourage research on non-mammalian models that could make unique contributions to the stated purpose. This announcement may be of particular interest to investigators who are using gene transfer into eggs and/or early embryos, twinning experiments, reproductive toxicology experiments and a variety of other experiments on the biochemical, physiological, morphological, genetic and molecular aspects of early mammalian development where eggs or embryos are maintained in vitro for any length of time.

This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

This program will be funded through the regular research grant (R01) award program of the NICHD. Grant applications will be reviewed as a single competition by an initial review group convened to review these applications. It is anticipated that 8-10 grants will be awarded.

Requests for copies of the full RFA should be addressed to:

Richard J. Tasca, Ph.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - Room 7C33
National Institutes of Health
Bethesda, Maryland 20205

Telephone: 301/496-6515

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HD-10

DEFINING AND SUBTYPING DYSLEXIA*

P.T. 34; K.W. 0715090, 0507005

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: September 15, 1985

I. SCIENTIFIC PROGRAM OBJECTIVES

The National Institute of Child Health and Human Development (NICHD), through the Human Learning and Behavior Branch (HLB), Center for Research for Mothers and Children (CRMC) invites program project applications (P01) for research programs which focus upon children who have inexplicable difficulty learning to read. Research applications should provide a plan for developing tests and measures of reading disability which will lead to standardization of criteria for selecting subjects for study. These criteria will provide bench mark indices for generating a cohesive data base which can be used to establish a biological and behavioral classification system for the reading disabilities.

II. MECHANISM OF SUPPORT

Multidisciplinary research on dyslexia (or specific reading disability) will be supported through the program project grant mechanism (P01).

*For purposes of this document, dyslexia and specific reading disability are equivalent terms.

This program is described in the Catalog of Federal Domestic Assistance under No. 13.865, Research for Mothers and Children. Awards will be made under authority of the Public Health Service Act, Title III, Section 301 (P.L. 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR, Part 52 and 45 CFR, Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

For further information, potential applicants may call or write to:

Dr. David B. Gray, HSA
Human Learning and Behavior Branch
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
Landow Building - Room 7C18
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20205
Telephone: (301) 496-6591

*For purposes of this document, dyslexia and specific reading disability are equivalent terms.

ANNOUNCEMENT

PARTICIPANTS SOUGHT

NATIONAL COLLABORATIVE CHEMOPREVENTION PROJECTS

P.T. 34; K.W. 0715035, 0740020, 0755025, 0710080, 0710100, 1003012, 1002008, 0710070, 0785165, 0755010

DIVISION OF CANCER ETIOLOGY

NATIONAL CANCER INSTITUTE

Chemoprevention is an important part of the National Cancer Institute (NCI) strategic plans. In the Division of Cancer Etiology (DCE), individual research grants and contracts are supporting efforts addressing fundamental issues in chemoprevention, such as the synthesis and discovery of anticarcinogenic agents, their efficacy in anticarcinogenesis, and the determination of their basic mechanisms of action. Many classes of chemopreventive agent are under investigation in numerous biological systems, and of these, a significant number appear promising for further development. In this regard, experience suggests that effective exploitation of new knowledge applicable to cancer prevention often requires diverse laboratory research expertise and material resources beyond the scope of most individual grants and contracts, and in many cases, beyond the capacity of single organizations. For these reasons, a request for applications (RFA) will soon be issued for National Collaborative Chemoprevention Projects (NCCPs) which are conceived as new approaches to cancer prevention in order to: acquire basic knowledge in significant biological systems for carcinogenesis/anticarcinogenesis; derive new insights into practical means for chemoprevention of the carcinogenic process; and rapidly translate these understandings into new chemopreventive entities with known ranges of efficacy and defined pharmacologic/toxicologic properties.

The Chemical and Physical Carcinogenesis Branch (CPCB), DCE, NCI is proposing to establish the NCCPs with funding provided through the cooperative agreement mechanism. The cooperative agreement is an assistance mechanism in which the Government component (NIH, NCI) making the award anticipates substantial programmatic involvement with the recipient during performance of the planned activity. Choice of actual funding mechanism will be made prior to issuance of the RFA. Each NCCP would consist of a number of laboratory research programs representing diverse scientific disciplines and expertise, such as experimental carcinogenesis, pharmacology, toxicology, medicinal and organic chemistry, molecular and cellular biology, biochemistry, immunology and pathology. Scientists in a given Project could derive from any combination of the academic, non-profit, and for-profit communities. Scientists in an NCCP could also be drawn from a single organization possessing necessary diversity and indepth expertise to accomplish Project objectives. Each Project is envisioned to consist of a Project Director, Program Leaders in several broad scientific disciplines and an NCI Coordinator. The Project Director has the responsibility for organizing the Project, assembling the multidisciplinary group of Program Leaders, preparing the cooperative agreement application and serving as Principal Investigator. This individual provides scientific and administrative leadership and, in addition, is expected to provide a laboratory program. A high degree of interaction and focus are expected in Project efforts.

It is anticipated that the scope of an individual NCCP might include: (1) in vivo efficacy determinations in significant biological models employed in carcinogenesis studies; (2) demonstration of feasibility of any in vitro bioassays employed, as related to in vivo carcinogenesis/anticarcinogenesis; (3) pharmacologic investigations of absorption, distribution, metabolism, and excretion with attention to dose/response relationships or investigations on the range of agent activity relative to organ sites at which chemoprevention is demonstrable and carcinogens/promoters against which activity exists; c) investigations characterizing the toxicologic properties of the agent; (4) biochemical investigations on mechanisms of action; and (5) investigations on structure-activity relationships elucidating chemical/structural features for agent efficacy, toxicity and pharmacologic properties.

The purpose of this initial announcement is to allow outstanding scientists who are interested in participating in the proposed Projects (either as Project Directors or Program Leaders) to identify themselves. The CPCB will organize and distribute this information within 30 days of closing to all who respond to this announcement. It is expected that this procedure will facilitate the efforts of individual scientists and organizations to identify other interested parties and to form strong interdisciplinary groups for the submission of applications for NCCPs. This present announcement is intended only to facilitate the formation of the Projects. An RFA will be issued shortly outlining the specifics of the National Collaborative Chemoprevention Projects. This RFA will be available to all investigators (organizations) as potential RFA responders whether or not they respond to the current announcement. The NCI will play no role in the formation of the Projects other than to distribute the information indicated above.

Scientists interested in participating in a NCCP, either as a Project Director or a Program Leader, should submit only the following information which will be tabulated and sent to investigators supplying information:

- 1) Name
- 2) Organization (including Department, mailing address and telephone number)
- 3) Scientific discipline
- 4) Participation interest (Project Director and/or Program Leader)
- 5) At the responder's option, one or two lines (more will be deleted) of brief descriptive information detailing the nature of the interest in participation. This might be simply a few keywords, if desired, such as: pancreas/anti-oxidants/structure activity/in vivo; or: mammary gland/hormonal/differentiation/any agents(s)

This information should be sent by June 3, 1985 to:

Carl E. Smith, Ph.D.
Program Director
Biological and Chemical Prevention
Chemical and Physical Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 9B-06
Bethesda, Maryland 20205

Telephone: (301) 496-4141

ANNOUNCEMENT

NCI COMPREHENSIVE MINORITY BIOMEDICAL PROGRAM

MINORITY INVESTIGATOR SUPPLEMENT (MIS)

P.T. 34, FF; K.W. 0715035, 0710030

NATIONAL CANCER INSTITUTE

I. DESCRIPTION

As part of the Comprehensive Minority Biomedical Program (CMBP), the National Cancer Institute (NCI) provides support for minority researchers in the form of the Minority Investigator Supplement (MIS).

Domestic research institutions already receiving NCI grants and interested in including minority researchers in their cancer research may submit an MIS application for this purpose. Approved applications will be funded as supplements to previously peer reviewed active grants. These may include, but are not limited to, individual project (R01) and program project (P01) grants.

II. OBJECTIVES

The CMBP provides support to minority scientists to assist in providing increased opportunities for enlarging their capabilities in cancer related research in order to influence minority scientists to develop independent careers as cancer investigators, while furthering the objectives of the parent grant.

III. PROJECT EVALUATION AND REVIEW CRITERIA

The NCI Program Director, in conjunction with the Cancer Minority Program Advisory Committee (CMPAC), will determine the appropriateness of the supplement to the grant and eligibility of the Minority Investigator using the following criteria:

1. The proposed research as described in the supplemental application should fit within the scope of the approved and funded project. If this is not the case, additional technical merit review will be required.

These programs are described in the Catalog of Federal Domestic Assistance Nos. 13.396, Cancer Biology; 13.393, Cancer Cause and Prevention Research; 13.399, Cancer Control; 13.394, Cancer Detection and Diagnosis Research; 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

2. The Minority Investigator's curriculum vitae should indicate that he/she has had appropriate research experience.
3. If the Minority Investigator has already spent an extended period of time in the applicant's laboratory, additional time should be justified.
4. The Principal Investigator and the Minority Investigator should demonstrate a clear understanding of the objectives of the MIS.
5. The length of time requested for achieving the objectives of the Supplement should be justified.

Following consideration by the NCI CMPAC, any application requiring additional technical merit review will be deferred for traditional peer review before any further consideration by CMPAC or the National Cancer Advisory Board.

IV. ELIGIBILITY

Any domestic institution with an active cancer research grant is eligible to submit a supplemental application on behalf of a principal investigator for the exclusive purpose of including minority researchers in the project.

- A. Minority Investigator - a Minority Investigator (MI) may be described as a U.S. citizen from an under-represented ethnic American nationality (e.g., Black, Hispanic, Native American, Asian or Pacific Islander). The MI is expected to provide a complete curriculum vitae which includes a list of any research publications. The MI(s) may be affiliated with the applicant institution(s) or some other institution. The MI should not have spent an extended period of time in the applicant laboratory and should not have been an independent investigator on any traditional grant mechanism from NIH or other funding organization. This does not exclude MI(s) who have been supported by the NIH Minority Biomedical Research Support (MBRS) Program or similar program. The program is not intended to pay stipends for student trainees or support candidates without any research background. The investigator must be willing to devote a minimum of 30 percent of his/her time to the research project.
- B. Research Project - the proposed research project for the supplement must be closely related to the currently funded research grant. It may represent an increased effort in an already approved objective of the research project or propose to enhance the effectiveness of the overall research. The nature of the research should provide the MI an opportunity to contribute intellectually to the program and to broaden his/her own potential. The scope of the project will generally be comprehensive enough to require at least two years for completion and the supplemental application should include such a research plan and projected budget sheets. With appropriate justification a one-year application may be acceptable. No new supplemental applications will be accepted in the final year of a current award.

V. FUNDING

Funding will be made in accordance with the usual NIH policy for supplements. Awards will be issued on an annual basis. Continuing support for the second (or subsequent) year will depend upon approval of a satisfactory annual progress report

and proposed budget from the MI submitted with the principal investigator's non-competing continuation application. Funding for the supplement is always contingent on funding of the parent grant. Each MI budget shall not exceed \$25,000 in direct costs and may not include equipment. Supplemental awards made under this program are for the sole purpose of facilitating participation by MI(s) as described above.

VI. HOW TO APPLY

All potential applicants are encouraged to call the NCI Minority Program office at (301) 496-7344 to receive complete clarification of any of the items noted above.

The Principal Investigator and the Minority Investigator should submit a supplemental grant application through the institution on the Standard Form PHS 398, limited to the following: (1) face page, at the top of which the applicant must designate the grant number of the active grant and specifically state "**Minority Investigator Supplement**" (for example, Grant Number CA-12345-02 "Minority Investigator Supplement"); (2) budget page (excluding equipment); (3) biographical sketch of the Minority Investigator; (4) outline of the research project as it relates to the parent grant; and (5) as part of the Significance section, the application should include a statement from the Minority Investigator outlining his/her research objectives and career goals and statement from the Principal Investigator describing how this research experience will expand the capabilities and foster the independent career of the Minority Investigator.

Applications received fewer than 90 days prior to a scheduled NCAB meeting may be reviewed at the subsequent NCAB meeting.

The original and four (4) copies of the application should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Please send two (2) copies to:

CMBP Program Director
Comprehensive Minority Biomedical Program
National Cancer Institute
Building 31 - Room 10A04
9000 Rockville Pike
Bethesda, Maryland 20205

ANNOUNCEMENT

NCI COMPREHENSIVE MINORITY BIOMEDICAL PROGRAM

MINORITY SATELLITE SUPPLEMENT

P.T. 34, FF; K.W. 0715035, 0755015, 0415000

NATIONAL CANCER INSTITUTE

I. DESCRIPTION

The National Cancer Institute (NCI) seeks to promote the participation of minority patients in clinical trials and other treatment programs at hospitals and institutions which serve large or predominantly minority populations through the Minority Satellite Supplement (MSS) of the Comprehensive Minority Biomedical Program (CMBP). This NCI interdivisional initiative seeks to identify institutions which could function as cooperative satellites of existing cooperative clinical trials groups and centers. The thrust of the initiative is to enter minority patients in an expanded and organized fashion, into clinical cancer treatment protocols. The improved level of cancer treatment should be reflected in improved survival and cure rates in minority cancer patients. A supplement would provide funding for data management and other relevant expenses. Currently funded clinical trials groups and centers interested in increasing minority patient enrollment into well-designed and well-implemented clinical trials may submit a supplemental application for this purpose.

II. OBJECTIVES

The NCI is committed to reducing cancer mortality by 50 percent by the year 2000. In order to achieve this objective, the Clinical Trials Research Network will be expanded to access a greater number of patients into programs researching the latest and most effective cancer treatment. Critical to this goal is the delivery of state-of-the-art cancer treatment to underserved minority populations. Cancer survival statistics verify that American blacks have substantially lower cancer survival rates than American whites with the same disease. By targeting segments of the population with the highest mortality, it is hoped that this interdivisional initiative will have a significant impact on minority population cancer treatment and survival. The MSS of the CMBP will contribute to NCI-supported clinical trials research groups to better enable the NCI's research to reach and support those minority populations which are particularly susceptible to cancer. It is not the purpose of the MSS to completely support an oncology program. Substantial local institutional support is a necessary prerequisite.

This program is described in the Catalog of Federal Domestic Assistance No. 13.397, Cancer Centers Support. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

III. PROJECT EVALUATION

The Divisional Program Director and the CMBP Director of the NCI will determine the appropriateness of the supplement request based on the applicant institution's ability to: (1) access adequate numbers of minority patients; (2) enter eligible patients on protocol; (3) deliver therapy; and (4) follow-up and report these patients. The proposed research described in the supplemental application must fit within the scope of the approved and funded parent project grant. Supplemental applications will be reviewed by the National Cancer Advisory Board for a final recommendation.

IV. ELIGIBILITY

Domestic institutions capable of accessing large numbers of minority patients on a regular basis, entering eligible patients on protocols, delivering therapy and following up patients may apply. These patients, largely Black, Hispanic, Native American and Oriental, have breast, prostate, cervical, lung, colon, head and neck cancers as predominant pathologies. As many of the patients would benefit from new methods of cancer treatment, the satellite institution would become an affiliate of an NCI-supported clinical trials program.

V. FUNDING

Funding will be made in accordance with the usual NIH policy for supplements. Awards will be issued on an annual basis for the duration of the project period of the parent award. Continuing support for each subsequent year of the project period will depend upon approval of a satisfactory annual progress report and proposed budget. Funding for the supplemental awards under this program is for the sole purpose of facilitating participation by institutions as described above. Institutions and hospitals funded by an MSS are not eligible for continued support under this mechanism beyond the project period of the parent grant.

VI. HOW TO APPLY

The named principal investigator on the active grant of a parent institution should submit an administrative supplemental application on the standard form PHS 398, limited to the following: (1) face page, in block 2, the application must designate the grant number of the active award and specifically state **"Minority Satellite Supplement;"** (2) budget page; (3) biographical sketch of the institutional satellite staff; and (4) the way in which current activities involving ongoing treatment protocols will be affected by accession of additional patients from the community at risk. Letters of support must be included by both the parent and satellite institutions from the Heads of the Department of Medicine or Deans, and Cooperative Group Chairmen where applicable.

The original and four copies of the application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Please send two copies to:

Dr. Lemuel Evans, Director
Comprehensive Minority Biomedical Program
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Building 31 - Room 10A04
Bethesda, Maryland 20205

ANNOUNCEMENT

RESEARCH GRANTS ON USE OF NEW TECHNIQUES TO STUDY METABOLIC PROCESSES AND DISEASES

P.T. 34; K.W. 0765020, 0715135, 1002008, 0790005, 0760030, 0760080, 1002028, 1014001

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Application Receipt Dates: July 1, November 1, March 1

I. INTRODUCTION

The Metabolic Diseases Research Program (Division of Diabetes, Endocrinology and Metabolic Diseases), supports basic research relevant to understanding the molecular and cellular mechanisms of inherited and acquired metabolic diseases. In accordance with recommendations from a recent Advisory Panel meeting, the Program encourages submission of research project grant applications (R01s and/or P01s), which propose to utilize new techniques in studies of enzymes and membranes, and their role in normal and abnormal metabolic processes.

II. RESEARCH GOALS

The goal of this research program is to encourage use of new tools to study basic mechanisms by which enzymes and membranes modulate or regulate chemical transformations and metabolic processes relevant to diseases of metabolism. The proposed studies should utilize one or more of the following techniques: recombinant DNA and/or gene transfer, hybridomas for antibody production, site-directed mutagenesis, patch-clamp single-channel recording, crystallization of intact membrane proteins, crystal data collection for x-ray analysis with two-dimensional electronic area detectors, or other novel and emerging techniques.

Recently developed technologies have the potential to bring about breakthroughs in understanding enzyme, protein and membrane structure-function as they relate to diseases of metabolism. For example, utilization of recombinant DNA techniques allows the analysis of regulation of expression of key enzymes and membrane receptor/transport proteins, and the expression of normal and mutant enzymes or membrane proteins in heterologous hosts for production of significant quantities of proteins. Production of specific and monoclonal antibodies by hybridoma technologies allows the isolation and purification of cellular and membrane proteins, and development of quantitation methods with diagnostic potential. Site-

This program is described in the Catalog of Federal Domestic Assistance, No. 13.847, Diabetes, Endocrinology, and Metabolic Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301, (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

directed mutagenesis allows the study of receptor and membrane transport systems, the genetic engineering of metabolic pathways "to order" in isolated cells or whole animals, or the design and production of new cellular or membrane proteins with altered receptor or transport properties. Patch-clamp single-channel recording allows characterization of ionic channels. Crystallization of membrane proteins makes possible high resolution structural analysis heretofore only possible for soluble proteins. Utilization of new two-dimensional electronic area detectors allows data collection for x-ray crystal diffraction studies in much shortened time frames.

Novel and important techniques, capable of contributing toward progress in the understanding, diagnosis and treatment of diseases of metabolism are continuously emerging. The Metabolic Diseases Research Program seeks to stimulate the use of these new and emerging technologies to advance our knowledge of enzymes, other proteins, and membranes relevant to metabolic diseases.

III. MECHANISM OF SUPPORT

Support for this program will be through the traditional research grant-in-aid mechanism. Successful applicants will direct and carry out the individual research projects. Program project applications must conform to an NIADDK imposed ceiling for total budget of \$1 million per year in direct costs when averaged over the requested project period. Applicants intending to submit new program project applications should consult with the NIADDK staff listed below and are strongly encouraged to submit a letter of intent, well in advance of the anticipated submission date, to permit careful fiscal and programmatic review.

IV. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on Form PHS 3983 according to instructions contained in the application kit. Application kits are available from most institutional business offices or may be obtained from the Division of Research Grants (DRG), NIH. Check "Yes" in item two on the face sheet of the application and type "Grants to Study Enzymes and Membranes in Metabolic Diseases" in the space provided.

- V. Applications must be responsive to the program announcement and the Abstract of the Research Plan should contain a clear statement relating the proposed research to inherited or acquired metabolic diseases of interest to NIADDK. Applications will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. Research grants (R01s) will be reviewed initially by an appropriate study section of the DRG. Program project grants (P01s) will be reviewed initially by an appropriate ad-hoc review group of the NIADDK. A second level of review for all applications will be performed by the National Arthritis, Diabetes, and Digestive and Kidney Diseases Advisory Council.

The original and six copies of the application should be mailed to the following address:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

A brief covering letter should accompany the application indicating that it is being submitted in response to this program announcement. A copy of this covering letter should be sent, under separate cover, to the Metabolic Diseases Research Program staff. For further information on areas of programmatic interest, investigators are encouraged to contact the following program staff:

Dr. Robert Katz
Director
Metabolic Diseases
Research Program, NIADDK
Westwood Building - Room 607
National Institutes of Health
Bethesda, Maryland 20205

or

Dr. Nancy Lamontagne
Assistant Director
Metabolic Diseases
Research Program, NIADDK
Westwood Building - Room 607
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7997

Telephone: (301) 496-4980

ANNOUNCEMENT

MINORITY INSTITUTIONAL RESEARCH TRAINING GRANT

P.T. 44, FF; -K.W. 0720005, 0715040, 0715165, 0785070

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: August 15, 1985

The National Heart, Lung, and Blood Institute (NHLBI) announces a program to train graduate students in minority schools for research careers in areas related to cardiovascular, pulmonary or hematologic diseases. The support mechanism will be the NIH institutional research training grant. Copies of the program guidelines are currently available from staff of the NHLBI, listed below.

Grants in this program will be made to minority institutions, each of which will cooperate with a research center that has a well-established cardiovascular, pulmonary, or hematologic research and research training program. Each trainee will be placed with a mentor who is an accomplished investigator at the cooperating research center and who will assist the advisor at the minority institution in the trainee's development and research plan.

Guidelines for this program may be obtained from any of the following:

George A. Hayden, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A10
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Joan M. Wolle, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A12
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance Nos. 13.837, 13.838 and 13.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 8-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Luis Barbosa, D.V.M.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5C06
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1537

ANNOUNCEMENT

MINORITY SCHOOL FACULTY DEVELOPMENT AWARD

P.T. 14, FF; K.W. 0715040, 0715165, 0750010, 0785070

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: August 15, 1985

The National Heart, Lung, and Blood Institute (NHLBI) announces a program to encourage the development of faculty investigators at minority schools in areas relevant to cardiovascular, pulmonary, blood diseases, and blood resources. Copies of the program guidelines are currently available from the staff of the NHLBI, listed below.

Grants in this program will be made to minority institutions on behalf of awardees, each of which will work with a mentor at a nearby (within 100 miles) research center, who is recognized as an accomplished investigator in the research area proposed and who will provide guidance for the awardee's development and research plan.

Guidelines for this program may be obtained from any of the following:

George A. Hayden, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A10
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Joan Wolle, Ph.D.
Division of Lung Disease
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A12
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance Nos. 13.837, 13.838, and 13.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.



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Luiz Barbosa, D.V.M.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5C06
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone (301) 496-1537

NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 14, No. 6 - May 24, 1985

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

Announcement

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ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

85-AI-05

STUDIES OF ACQUIRED IMMUNODEFICIENCY SYNDROME

P.T. 34; K.W. 0715120, 0785055, 0745055, 0755015, 0411005

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: September 15, 1985

I. BACKGROUND INFORMATION

Because of its mission to support research in immunology and infectious diseases, the NIAID has played a central role in the investigation of the Acquired Immunodeficiency Syndrome (AIDS), an infectious disease of the immune system. Since the discovery of the retrovirus HTLV-III/LAV as the etiological agent of AIDS, research efforts directed toward the epidemiology, prevention, pathogenesis, and adequate treatment of both the underlying disease and its sequelae have been intensified.

Since 1981, NIAID, in collaboration with other Government agencies, has supported research grants, cooperative agreements and contracts aimed at clarification of a variety of AIDS-related issues. This present announcement is designed to encourage continuation and extension of AIDS research efforts taking advantage of the ever-expanding knowledge base. It is intended that these efforts will be conducted in the context of a "Working Group;" i.e. a group of institutions carrying out various research projects funded as a result of the RFA or other mechanisms. Consistent with the Cooperative Agreement mechanism, NIAID Staff will serve as a resource of information and work to facilitate exchange of information and material among involved investigators. It is NIAID's assessment that such collaboration between investigative groups will rapidly and efficiently enhance achievement of the goals of the RFA; i.e., definition of the biology of the etiologic agent, clarification of the pathogenesis and immunologic mechanisms of the disorder, and improvement of prevention and treatment, including immune reconstitution. It is emphasized that this RFA is designed to accommodate both new and renewal applications in this programmatic area.

II. RESEARCH GOALS AND SCOPE

Studies proposed should stress innovative approaches to the problem and should include and/or emphasize any or all the following:

- A. Epidemiologic studies, particularly those designed to identify risk factors or determinants (behavior, drug use, etc.) of the disease manifestations of AIDS or AIDS Related Complex in individuals at risk.

- B. Laboratory research on the pathogenesis, treatment, and prevention of AIDS. Projects could include in vitro or in vivo studies of the biology of HTLV-III/LAV, interactions of HTLV-III/LAV with other infectious agents or cofactors, development of assays for antigen detection, and development of animal models, antiviral agents and vaccines. Projects could also include studies of affected immune system components leading to loss of function and disturbances in immunoregulatory balance.
- C. Clinical trials to treat or prevent HTLV-III/LAV infection, the resultant opportunistic infections or repair the immunologic deficiency in AIDS patients. Efforts to reconstitute the patients' immune system could include immune interferon, interleukin-2, other amplifiers of T and/or B lymphocytes, bone marrow transplantation, histocompatible lymphocyte transfusions, or other approaches.

III. MECHANISM OF SUPPORT

Awards will be made as Cooperative Agreements. These are assistance awards requiring substantial involvement by NIAID Staff. NIAID anticipates making multiple awards as a result of this request; it is expected that a total of \$1,000,000 will be allocated for funding the first year's awards. Awards will be generally made for project periods of three to five years. All policies and requirements which govern the PHS grants programs apply.

IV. STAFF CONTACT

Investigators seeking information relevant to the infectious disease aspects should contact:

Harry W. Haverkos, M.D.
Clinical and Epidemiologic Studies, MIDP
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Building 31 - Room 7A-51
Bethesda, Maryland 20205

Telephone: (301) 496-5893

For information concerning the immunologic aspects, applicants should contact:

Robert A. Goldstein, M.D., Ph.D.
Chief, Immunopathology Branch, IAIDP
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 755
Bethesda, Maryland 20205

Telephone: (301) 496-7104

A more detailed version of this request is available from either of these contacts. Prospective applicants also are encouraged to submit to the appropriate Staff contact a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. The NIAID requests such letters by July 15, 1985, for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding. It will not enter into the review of any application subsequently submitted and is not a necessary requirement for application.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS

85-CA-13

CLINICAL EVALUATION OF MODELS OF BIOCHEMICAL MODULATION

P.T. 37; K.W. 0745005, 0755020, 0755015, 0740015, 0710100

NATIONAL CANCER INSTITUTE

Application Receipt Date: September 15, 1985

The National Cancer Institute's (NCI), Division of Cancer Treatment, invites applications for cooperative agreements to support a program of laboratory and clinical investigations directed toward the development and optimal clinical use of a combination of drugs which is synergistic *in vitro*.

I. BACKGROUND

The synergistic interaction of drugs at a biochemical level has been demonstrated in both *in vitro* and *in vivo* systems. These leads have not been successfully applied to clinical trials in a rational and systematic manner. Studies which reproduce in the clinical setting the preclinical conditions necessary for optimal synergy have not been performed. Synergy of two agents in murine tumors has previously been the justification for combining such agents in clinical trials. However, the design of these trials has failed to translate accurately dosage and scheduling considerations from the *in vitro* and preclinical *in vivo* models to the clinic. The potential for defining and maximizing the synergistic interaction of antitumor agents can only be realized by careful study in the preclinical setting, and by confirming and refining this interaction through detailed biochemical studies in the initial clinical trials. Having established in Phase I trials the optimal doses and schedules to maximize both synergy and selectivity in this manner, the regimen should then be carried forward in appropriate comparative trials. The execution of such trials requires a major commitment of resources by both clinician and laboratory scientist. The experimental findings of each will modify the design and conduct of the other's study. Strong program planning under a single funding instrument is required to effect the integration of laboratory and clinic.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

II. RESEARCH GOALS AND SCOPE

Proposed studies should emphasize:

- A. Delineation of the mechanism of modulation at a molecular level in an in vitro setting;
- B. Measurement of the antitumor efficacy of such combinations in in vitro systems.
- C. Confirmation and validation of this enhanced efficacy and where feasible the mechanism of modulation at an in vivo preclinical level, and refinement of the therapeutic index based on any new in vivo findings.
- D. Advancement of the combination into clinical testing, and in such trials to establish that the projected modulation is indeed occurring in the target tissue, examine the pharmacokinetics and pharmacodynamics of such schedules for later activity trials, and describe the alteration in selectivity by the modulation at a biochemical and clinical level.

The awardees will participate in the NCI sponsored drug development meetings three times a year in order to review progress, to plan and design research objectives, to establish priorities and to promote the development of collaborative arrangements between investigators. This will facilitate the step-wise progression of the awardee's proposed plans for biochemical modulatory development. NCI staff will serve as a resource of information and will work to facilitate exchange of information and material and collaboration between involved investigators.

Many of the NCI sponsored IND drugs are leading candidates with biochemical modulatory properties. Applications are encouraged which focus on these NCI sponsored IND drugs in order to provide leads to the most rational use of these chemotherapeutic agents in the treatment of cancer patients.

III. MECHANISM OF SUPPORT:

Awards will be made as Cooperative Agreements. These are assistance relationships involving substantial involvement of NCI staff during performance of the project. The terms of NCI staff participation are included in the complete RFA.

NCI anticipates making multiple awards as a result of this request. It is anticipated that \$750,000 will be set aside to fund the initial year's awards. Awards will be made for a period of up to five years. It is anticipated that the starting date for the initial annual period will be between April 1, 1986 and July 1, 1986. No set-aside funds have been provided for renewals.

All policies and requirements that govern the grant program of the U. S. Public Health Service apply, including the requirement for cost sharing. Although this program is provided for in the financial plans of the NCI, the award of cooperative agreements pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. STAFF CONTACT

A copy of the complete RFA describing the research goals and scope, the nature of NCI staff participation, the review criteria and method of applying can be obtained by contacting:

Ann Carpenter
Program Administrator
Cancer Therapy Evaluation Program
National Cancer Institute
Landow Building - Room 4C33
Bethesda, Maryland 20205

Telephone: (301) 496-8866

ANNOUNCEMENT

RENEWAL OF CLINICAL INVESTIGATOR AND PHYSICIAN SCIENTIST AWARDS

P.T. 34; K.W. 1200180, 1200270

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates August 1, 1985,
and June 1 in subsequent years

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of competitive renewals of Clinical Investigator Awards and Physician Scientist Awards to assist awardees in achieving the status of independent investigator. In view of the limited amount of research training and/or research experience that most awardees have at the beginning of the award period, the Institute recognizes that some individuals may need up to three additional years to become independent investigators with adequate research grant support.

Clinical Investigator and Physician Scientist awardees may request a three year renewal of their awards if they meet all of the following conditions:

- o Awardees are not recipients of a Research Career Development Award or an Academic Award.
- o Awardees will devote at least 50 percent effort to heart, lung, and/or blood research during the renewal period.
- o The grantee institution makes a commitment to provide the necessary facilities and resources and submits the competing application.

Guidelines for the renewal will be mailed to NHLBI Clinical Investigator and Physician Scientist awardees. The guidelines will include directions for completing the renewal application and criteria to be applied in the review of renewal applications.

For further information, NHLBI Clinical Investigator and Physician Scientist awardees may contact the program staff shown on their Notice of Grant Award at the following addresses:

Fann Harding, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5A08
Bethesda, Maryland 20205

Telephone: (301) 496-1817

Max A. Heinrich, Jr., Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A12
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Joan Wolle, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 612A
Bethesda, Maryland 20205

Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance No. 13.839, Blood Diseases and Resources; No. 13.837, Heart and Vascular Diseases; and No. 13.838, Lung Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ANNOUNCEMENT

PREVENTIVE ONCOLOGY ACADEMIC AWARD

P.T. 34; K.W. 0785140, 0745055

NATIONAL CANCER INSTITUTE

Competition for the Preventive Oncology Academic Award (K07) is being resumed. There will be one receipt date annually, namely October 1. Please write or call the person listed below to discuss your interest in this program and obtain a copy of the program guidelines to use in writing an application. Again, please note that the next receipt date is October 1, 1985.

Please address inquiries to:

Program Director, K07
Cancer Training Branch, CCSP, DCPC
National Cancer Institute
Blair Building - Room 424
Bethesda, Maryland 20205-4200

Telephone: (301) 427-8898

ANNOUNCEMENT

ASSESSMENT OF MENTAL HEALTH PROBLEMS IN DISASTER VICTIMS

MH-86-03

P.T. 34; K.W. 0715095, 0785055, 0404021, 0715210, 0413000

NATIONAL INSTITUTE OF MENTAL HEALTH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

The purpose of this announcement is to encourage researchers to estimate the type and the incidence of mental health disorders, including Post Traumatic Stress Disorder, resulting from exposure to disaster; to study factors associated with the development and continuance of these disorders in victims exposed to different types of disaster events; and to assess changes in life functioning and other early behavioral problems following disaster exposure which may or may not lead to a mental health disorder.

A new instrument, the Diagnostic Interview Schedule/Disaster Supplement (DIS/DS) is designed to provide a comprehensive picture of the emergency experience and is applicable across a wide range of emergencies. The instrument assesses the type of emergency, type and extent of loss, individual and family risk factors, use of formal and informal support systems, and psychosocial and behavioral response to the traumatic event.

Several activities are under way for users of the DIS/DS to facilitate standardized assessment and cross-study comparisons of the mental health effects of different types of emergencies. The core of the instrument is the Diagnostic Interview Schedule (DIS), a comprehensive instrument originally covering 34 DSM-III diagnoses. Incorporated into the DIS during the ECA studies were questions about generalized anxiety, Post Traumatic Stress Disorder, and traumatic life events, a standardized supplement describing use of medical services, family history of disorder, assessments of social support, and functioning levels in occupational and interpersonal arenas.

In the course of adapting the DIS for use in disaster situations, questions regarding disorders of low incidence or irrelevance to the disaster experience were eliminated. The Disaster Supplement (DS) adds questions about disaster exposure, including such factors as damage, losses, news coverage, attributions for the event, and traumatic response of significant others.

This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Mental Health Research Grants. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The object of this announcement is to encourage, stimulate, and support studies that will use the DIS/DS for disaster-related investigations of interest to the applicants. Applicants may add measures of particular relevance to their study and adapt the DIS/DS to the emergency in question. Applications should have as their focus a particular mental health issue rather than a particular emergency event, allowing for review, approval, and funding prior to the emergency.

To be accepted for review, applications should:

- o Propose a clearly discernible research activity, involving generation and testing of hypotheses.
- o Demonstrate clear and direct relevance to the mental health of victims, their families, and/or significant others.
- o Be prospective epidemiological surveys, collecting at least two waves of longitudinal data following disaster impact: near-immediate assessment and assessment one year after impact.
- o Articulate rationales for either substituting, supplementing, or omitting portions of the DIS/DS, in terms of the instrument's relation to the population and type of emergency event to be studied.
- o Indicate the problem area, the research design, and the characteristics of the emergency situation for which the objectives and methodology would be appropriate.
- o Include a comparison group of respondents selected in such a way that a significant theoretical question can be tested.
- o Indicate the extent to which the assessed dimensions will permit generalization.
- o Include a designated advisory group of three to five members for scientific oversight, selected on the basis of experience in conducting studies of emergencies.
- o Articulate procedures established to insure that the project advisory group will be available to fulfill its function and that the project team will be able to mobilize its resources at the time of the emergency event.

Applicants should be concerned with projects with substantive emphasis on any one or more of the following areas:

- o Studies of different population subgroups in order to establish differential risk of negative effect.
- o Studies which examine families as interactional systems in their response to emergency situations.
- o Studies of immediate and long-term mental and physical health impact of disaster on individual victims and their significant others.

- o Studies of the mental health consequences of perceptual aspects of traumatic events, such as extreme fear, perceived aspects of responsibility, perception of lasting consequences, and expectation of the recurrence of such an event.
- o Studies of the mental health consequences of treatment of victims by non-mental health community and Federal agencies.
- o Studies of both short-term crisis intervention and long-term mental health treatment and service delivery for victims of all ages and/or their significant others.
- o Studies of social support systems and coping mechanisms as mediators of psychological response to emergency events.

NIMH research grants are available to any public or nonprofit institution such as a university, college, hospital, or community agency, units of State or local government, and authorized units of the Federal Government and to for-profit institutions and entities.

Applications submitted in response to this announcement will be reviewed in accordance with the usual Public Health Service peer review procedures for research grants and in accordance with the usual NIMH receipt, review, and award schedule.

Review criteria include the significance and originality of the research goals; the state of knowledge in the field; the feasibility of the research; the competence and dedication to the project of the principal investigator and his or her supporting staff; the adequacy of available facilities; the potential usefulness, generalizability, or heuristic value of the results; provision for the protection of human subjects; and the appropriateness to the proposed budget for the work outlined.

Initial review group and National Mental Health Advisory Council recommendations, program balance in type of emergency event, and availability of funds are taken into consideration in determining which projects will be funded.

For terms and conditions of support, application procedures, and a copy of the DIS/DS to be used for responding to this announcement, applicants may contact:

Susan Solomon, Ph.D. or Mary Lystad, Ph.D.
Center for Mental Health Studies of Emergencies
5600 Fishers Lane, Room 6C-12
Rockville, Maryland 20875

Telephone: (301) 443-1910

ANNOUNCEMENT

RESEARCH ON FAMILY STRESS AND THE CARE OF ALZHEIMER'S DISEASE VICTIMS

MH-86-07

P.T. 34; K.W. 0715180, 0715195, 0730010, 0715095, 0415000, 0730050

NATIONAL INSTITUTE OF MENTAL HEALTH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

The National Institute of Mental Health (NIMH) through the Center for Studies of the Mental Health of the Aging (CSMHA) seeks applications for studies which will increase knowledge and improve research methodology on family stress related to the care of individuals with Alzheimer's disease (AD) and the development of family care and service delivery models. Applications should focus on the generation of systematic information on the nature, consequences, and interplay of stress associated with caregiving; factors associated with understanding and enhancing family support; the identification, treatment, and management of excess disability in AD patients and strategies to maximize their functional level at all stages of the disease; the prevention of psychopathology and the promotion of mental health among family caregivers; and research on the design and delivery of services which provide treatment and clinical interventions for individuals with AD and for the family members who care for them.

I. TOPICS OF RESEARCH INTEREST

Specific research topics of interest include but are not limited to:

- o Studies of the nature, consequences, and interplay of stress associated with caregiving on the individual family caretaker, family unit, and the AD patient
 - nature of risk factors associated with the development of stress-related dysfunction in individual caretakers and family units
 - nature of short- and long-term physical, psychological, social and financial consequences of family caretaking, particularly studies on the development or exacerbation of physical (e.g., diabetes, hypertension) or psychological conditions in the caregiver
 - the interaction of family stress, coping strategies, and the management of the AD patient
 - stress and bereavement in the context of the clinical course of AD
- o Systematic research on family support, broadly conceived
 - investigations of the nature, type, and extent of family support

- identification and analysis of individual and family characteristics, interactions, and other variables most amenable to the particular caretaking functions associated with AD, including the identification of factors associated with caregiver satisfaction, positive aspects of caregiving experiences, and effective coping strategies
 - determination of the efficacy of and best approaches to teaching behavioral management or other strategies to caregivers and development of valid assessment instruments
 - identification and development of strategies to aid the family in the early recognition of symptoms, the decision to seek medical care, and the decision to assume and play a primary caregiver role
 - identification of the most effective coping strategies and interventions used by caregivers; and identification of the kinds of information, education, support, and treatment that best reinforce the increased coping abilities of families with AD members.
- o Systematic research aimed at the treatment and management of excess disability and the maximizing of AD patients' functional level
- examination of factors in the psychosocial and physical environment which shape and maintain positive behaviors in AD patients
 - development of strategies to maximize the functional level of the AD patient, at all stages of the disease, through the application of mental health treatment modalities
 - development of new approaches for managing behaviors most frequently leading to institutionalization
 - identification and reduction of excess disability, including accurate diagnosis and treatment of coexisting physical and psychiatric symptoms
- o Systematic research on the prevention or reduction of psychopathology, symptoms caused by stress, and the promotion of mental health among family caregivers
- the effectiveness of supportive interventions for the primary caregiver and other family members
 - development of methodologies for assessing specific types of interventions for preventing/moderating stress among family caretakers
- o Systematic research on the design and delivery of services and service systems for AD victims and their caregivers
- identifying an optimal range of community and institutional services relevant to AD in terms of design, staffing, timing of use during the progression of the disorder, mix, and coordination with other services

- studies of the best methods of delivering services such as comprehensive assessment, case (care) management, outpatient treatment, home health care, respite care, adult day care, partial hospitalization, and nursing home care
- strategies for the most effective integration of formal support services provided by health care professionals with informal support interventions provided by family, friends, and neighbors
- application of research in the development of new services for AD patients
- services research demonstration aimed at developing models for providing a state-of-the-art clinical management, treatment, and care, taking into consideration the context of where treatment and services are provided (e.g., the home, the community, a nursing home)

II. ELIGIBILITY

Private, nonprofit, or for-profit and public institutions, such as units of State or local government and authorized units of the Federal Government (including Veterans Administration hospitals and other facilities), are eligible to apply for grants under this announcement.

III. REVIEW

Applications will be reviewed according to the regular NIMH review schedule and according to the standard review procedures of the Public Health Service.

Criteria for scientific/technical merit review will include the following:

- o Scientific or technical significance of the goals of the proposed research
- o Adequacy of the methodology proposed to carry out the research
- o Qualifications and experience of the principal investigator and proposed staff
- o Potential contributions to the objectives and scope of this announcement
- o Adequacy of the conceptual and theoretical framework for the research
- o Evidence of familiarity with relevant research literature
- o Scientific merit of the research design, approaches, and methodology
- o Adequacy of the data analysis plan
- o Adequacy of the existing and proposed facilities and resources
- o Appropriateness of the budget, staffing plan, and timeframe to complete the project
- o Adequacy of proposed procedures for protecting human subjects

IV. AWARD CRITERIA

In making decisions to fund applications, the following will be considered:

- o Quality of the proposed project as determined during the review process
- o Availability of funds
- o Balance among research areas of the announcement

V. STAFF CONSULTATION

For further information concerning terms and conditions of support, and application procedures and assignment, applicants should contact:

Enid Light or Barry D. Lebowitz, Ph.D.
Center for Studies of the Mental Health of the Aging
National Institute of Mental Health
5600 Fishers Lane, Room 11C-03
Rockville, Maryland 20857

Telephone: (301) 443-1185



3 1496 00160 8853

NIH Guide for Grants and Contracts

Vol. 14, No. 7, June 21, 1985

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

To All Concerned With National Research Service Awards (NRSA)

P.T. 22, K.W. 0720005

We have had many inquiries about the erroneous statement concerning the taxability of NRSA stipends which appeared in Publication 520 (Rev. Nov. 84) Scholarships and Fellowships.

A correction to publication 520 appeared in the March 12, 1985 (1985-8) Tax News issued by the Department of the Treasury, Internal Revenue Service. It reads:

"1. Correction to Publication 520

Publication 520, Scholarships and Fellowships, (revised November 1984) states that National Research Service awards received after 1983 by individuals under the Public Health Service Act of 1974 are not treated as scholarships or fellowship grants (which are excludable under section 117 of the Internal Revenue Code). This is incorrect. On the basis of a 1981 amendment to the Act, the awards are now treated as excludable from the recipients' gross incomes as scholarships or fellowship grants.* See Rev. Rul. 83-93, 1983-1 C.B. 364, which revoked Rev. Rul. 77-319, 1977-2 C.B. 48."

*Underlining added for emphasis

NOTICE

MORATORIUM ON ACCEPTANCE OF PROGRAM PHYSICIAN SCIENTIST AWARD APPLICATIONS

P.T. 34; K.W. 1014002

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Beginning with the October 1, 1985 application receipt date, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) will no longer accept new or amended applications for Program Physician Scientist Awards. It is hoped that competing applications can again be accepted for review and possible funding at a future time.

Applications for individual Physician Scientist Awards will continue to be accepted by NIADDK.

NOTICE

FIVE YEAR PROJECT PERIODS FOR NIADDK CENTER GRANTS

P.T. 04; K.W. 1014002

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) supports a number of groups of investigators through the use of research center grant mechanisms. Currently, three such mechanisms are in use: the Comprehensive Research Center (P60), the Specialized Center of Research (P50), and the Core Center (P30). It has become increasingly clear that center grants awarded for project periods of less than five years are not optimal, and the NIADDK is adopting a policy of fixing the project periods of all center awards at five years except under very unusual circumstances. Beginning with the application receipt date of October 1, 1985, all applications for center awards assigned to NIADDK must request a project period of five years. Review groups will be instructed that special justification must accompany recommendations of project periods of less than five years. Similarly, individual components and core units should be approvable for periods of five years except under unusual conditions. Applicants proposing pilot and feasibility studies of one, two, or three years in duration should consult NIADDK staff regarding the appropriate format for proposing a five year program of such studies

The NIADDK believes that this policy will increase both efficiency and effectiveness of research activities supported by center grant mechanisms. Questions regarding this policy should be directed to:

Dr. Walter S. Stolz, Director
Division of Extramural Activities,
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
5333 Westbard Avenue - Room 657
Bethesda, Maryland 20205

Telephone: (301) 496-7277

NOTICE

ADAMHA PEER REVIEW APPEALS SYSTEM

P.T. 34, 44; K.W. 1014002

**ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTE OF MENTAL HEALTH**

The Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) has initiated an appeals process whereby applicants may request an examination of their concerns about the referral and peer review of their applications for research grants, research training grants and fellowships, and cooperative agreements for research.

This process is intended to resolve those concerns which arise from perceived shortcomings or errors in the substance or procedure of peer review—i.e., from receipt and assignment of an application through its review by a National Advisory Council. Such concerns may involve refusal to accept an application; a disputed assignment of the application to an initial review group or to a particular Institute; perceived insufficient expertise on the initial review group or site visit team or conflict of interest on the part of one or more members; apparent factual or scientific errors, oversights, or bias associated with the review of an application at the initial or advisory council review; and perceived inappropriate handling of the review of the application.

However, the appeals process is not intended to resolve purely scientific disputes between peer reviewers and the investigator; to provide a mechanism for allowing investigators to submit information that should have been presented in the original proposal; or to provide a forum for disputing priority score determinations in the absence of specific and substantive evidence pointing to a flawed review.

The appeals process will not supersede or bypass the peer review process, but if serious shortcomings are found to have occurred in the review of an application, they will be rectified by one of the following actions: re-review by the same or another initial review group; special consideration by the advisory council; or administrative action authorized by the Institute Director or designated staff.

As in the past, investigators are urged to communicate and discuss their concerns regarding peer review with appropriate staff. Now, if investigators are still dissatisfied after a response is received to their communications, they also may request a further examination of these concerns.

Under the appeals system, all concerns must first be communicated to the unit which at the time is responsible for the application. Appropriate officials will thoroughly examine the investigator's concerns, frequently with the help of the initial reviewers or other experts, and, if shortcomings are found to have occurred, every effort will be made to rectify them in a timely manner.

If the principal investigator disagrees with the resolution of his/her concerns by the responsible Institute staff, an appeal, jointly signed by the PI and applicant organization, may be sent to the designated Institute Appeals Officer whose name and address appears

below. The appeal must include documentation of the original dispute, previous communications and interactions with staff in relation to the dispute, and a clear statement of the reasons for disagreeing with the resulting decision. To allow for a complete and independent examination of the appeal--which will frequently entail consultation with scientific or other experts--the application will be withdrawn from the regular review process until the appeal is resolved. An amended application submitted during consideration of the appeal will inactivate the original application and the accompanying appeal. The Institute Director will render the final decision on the appeal and communicate it to the applicant.

HOW TO USE THE APPEALS SYSTEM:

Communications before the Initial Review

After being notified about the assignment of an application to the initial review group and the awarding Institute, the principal investigator may direct his/her serious concerns about the assignment of the application to the ADAMHA Grants Referral and Review Officer, 5600 Fishers Lane, Room 13-103, Rockville, Maryland 20857. Concerns about the pending review of the application should be directed to the Executive Secretary of the assigned initial review group.

Communications after the Initial Review

After having received the summary statement, the principal investigator may direct his/her questions about the review to the Executive Secretary, who will respond or refer the communication to the appropriate person for response. Communications may be submitted at any time, including after National Advisory Council review, but investigators are encouraged to communicate their concerns as early as possible.

Appeals

After having received the reply to a communication, and if the principal investigator disagrees with the decision, he/she and the applicant organization may appeal by submitting the necessary documentation to the appropriate Institute Appeals Officer:

NIAAA

Deputy Director
National Institute on Alcohol and Alcoholism
Room 16-105

NIDA

Executive Officer
National Institute on Drug Abuse
Room 10-15

NIMH

Associate Director for Extramural Programs
National Institute of Mental Health
Room 17C-26

All of the above are located in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Effective Date

This appeals system is effective upon issuance of this notice for applications assigned to September 1985 National Advisory Councils.

Comments

Comments are invited on this policy which will be evaluated after some experience has been gained with using the appeals system.

ERRATA

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS:

85-CA-13

CLINICAL EVALUATION OF MODELS OF BIOCHEMICAL MODULATION

P.T. 37; K.W. 0745005, 0755020, 0755015, 0740015, 0710100

NATIONAL CANCER INSTITUTE

Application Receipt Date: September 15, 1985

Please correct paragraph 3 under II. RESEARCH GOALS AND SCOPE as follows:

Many of the NCI sponsored IND drugs are leading candidates with biochemical modulatory properties. Applications are encouraged which focus on these or other drugs with biochemical modulatory properties. We expect the results of these studies to be published in the scientific literature in order to provide leads to the most rational use of these chemotherapeutic agents and to improve the treatment of cancer patients.

Please correct paragraph 2 under III. MECHANISMS OF SUPPORT as follows:

NCI anticipates making multiple awards as a result of this request. It is anticipated that \$750,000 will be set aside to fund the initial year's awards. Awards will be made for a period of up to five years. It is anticipated that the starting date for the initial annual period will be between July 1, 1986 and September 30, 1986. No set-aside funds have been provided for renewals.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-19

DIFFERENTIATING AGENTS IN HUMAN MALIGNANCIES

P.T. 34; K.W. 1002004, 0760020, 0740020, 0785035

NATIONAL CANCER INSTITUTE

Application Receipt Date: October 15, 1985
Letter of Intent Receipt Date: August 15, 1985

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites grant applications from interested investigators for a tightly focused, cohesive research program at the interface of basic research and concurrent clinical trials involving differentiating agents in human tumors.

A series of clinical observations has led to the current interest in differentiating agents as potential therapy for human malignancies. The current concept that cancers are composed of cells blocked at an early stage of normal maturation has stimulated a search for agents with potential differentiating effects. Such agents are particularly attractive since, in principle, they should have few effects on normal tissue and therefore, avoid many of the toxicities of chemotherapy or radiation therapy. Retinoids were one of the first classes of agents studied and were observed to induce differentiation in a number of in vitro systems. A wide range of compounds have subsequently been discovered, including polar solvents, fatty acids, vitamin D analogues, and several cytotoxic agents (pyrimidines, purines, anthracyclines) which cause differentiation in vitro at doses below the cytotoxic level. A broad spectrum of cellular alterations has been observed after treatment of established human tumor cell lines with these compounds. In most cases, however, there is no clear cause and effect relationship and the specific sites of growth control at the cellular level remain obscure.

Such in vitro observations have led to sporadic, empirical clinical trials of several differentiating agents. These trials, however, have yielded conflicting results and have methodologic flaws. For example, with similar schedules of low doses of Ara-C, complete response rates in acute leukemia and myelodysplastic syndromes range from 10% to over 50%; the drug has appeared to act as a maturational agent in some series and as a cytotoxic agent in others. There are several possible explanations for these and other discrepancies. First, the tumors which have been most frequently studied include

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Acute Myelocytic Leukemia (AML), myelodysplastic syndromes, and neuroblastoma, which are relatively uncommon, and important subgroup analyses have been lacking. Second, there are at present no clearcut biochemical effects for these agents at the cellular level which have been correlated with clinical efficacy. Indeed, there are limited data as to the clinical relevance of any of the laboratory phenomena described thus far. The central issue is the lack of methodology which permits distinguishing between cellular differentiation and cytotoxicity followed by regeneration.

Thus, while there is a substantial amount of ongoing basic research and an obvious timeliness for entry of potential differentiating agents into organized clinical trials, currently, there are limited, spontaneous correlative studies ongoing and many tumor types and laboratory techniques remain unaddressed. The accurate and precise measurement of treatment effect at a clinical level remains a serious problem in clinical trial design. Research directed at the development of such measures, based on accumulated pre-clinical experience, is an essential step in further clinical research.

I. RESEARCH GOALS AND SCOPE

Studies should be proposed for a tightly focused, cohesive research program at the interface of basic research and concurrent clinical trials involving differentiating agents in human tumors. These studies should emphasize:

- 1) Laboratory exploration of in vitro/in vivo systems for measuring differentiation/maturation that could have clinical applicability; and
- 2) Establishment of the validity of these measures in the clinical setting.

Applications will be sought which will develop laboratory-clinical interactions.

II. LETTER OF INTENT

A potential applicant institution is encouraged to submit a one-page letter of intent, including a brief synopsis of the proposed research Dr. Bruce Cheson on or before August 15, 1985 and to consult with NCI staff before submitting an application. A letter of intent is not binding, is not a requirement for consideration, and does not enter into the review of a subsequent application.

III. STAFF CONTACT

A copy of the RFA describing the research goals and scope, the review criteria and method of applying can be obtained by contacting:

Dr. Bruce Cheson
Senior Investigator
Clinical Investigations Branch
Cancer Therapy Evaluation Program
National Cancer Institute
Landow Building - Room 4A14
Bethesda, Maryland 20205

Telephone: (301) 496-2522

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA85-HD-11MECHANISMS OF IMMUNOLOGIC INFERTILITY

P.T. 34; K.W. 0413002, 0710070, 0710065, 0710075

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: October 15, 1985

The Reproductive Sciences Branch (RSB) of the Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD) announces the availability of a Request for Applications (RFA) on Mechanisms of Immunologic Infertility. The purpose of this initiative is to stimulate research in an area important to the CPR mission that is currently not supported at appropriate levels. The need for increased research in this area rises from the significant increases in human infertility rates over the last decade. Between 1980 and 1982 alone, physician office visits for infertility problems rose from 900,000 to over 2 million. It has been estimated that infertility secondary to immunological factors may occur in 15-20 percent of couples with unexplained infertility. In a significant subset of infertile couples, therefore, it appears that immunologic infertility is a circumstance for which effective therapy has not been clearly established.

The RFA being announced is specifically designed to encourage research on the immunology and immunogenetics of sterility, subfertility, or infertility in mammals. Responsive applications would include, for example, those focusing on immunologically-based functional or dysfunctional processes of mammalian gonads, gametes or reproductive tract tissues that are directly involved in gamete production or maturation, fertilization, preimplantation embryo survival and transport, or conceptus implantation processes. Excluded from responsiveness to this announcement's intent would be studies directly related to the processes of malignancies or sexually transmitted diseases, prenatal diagnosis via chorionic or amniotic cell analyses, perinatal immunology, acquired immune deficiency disorders, and general studies of autoimmune or endocrine disease aspects unrelated to direct mechanisms of infertility. It is not the intent of this announcement to solicit research proposals designed to conduct general studies of

This program is described in the Catalog of Federal Domestic Assistance number 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

autoimmune diseases or immunological disorders. In the absence of a major, extensive, and predominant emphasis on infertility or fertility, such applications would not be considered responsive to the RFA. This announcement should be of particular interest to investigators concerned with 1) the detection, definition and characterization of hormone, sperm, or egg antigens associated with critical events or processes of gamete production or function; 2) the detection, definition, or characterization of immune system mediated early conceptus implantation failures; 3) the immunopathology of immune or autoimmune ovarian or testicular failure; or 4) the immunological consequences of gonad transplantation.

It is anticipated that up to eight (8) awards will be made as a result of this announcement through the grant-in-aid (R01) mechanism used by NICHD. Grant applications will be reviewed as a single competition by an initial review group convened by the Division of Research Grants (DRG), NIH.

Requests for a more detailed RFA and information inquiries should be addressed to:

Michael E. McClure, Ph.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - Room 7C33
Bethesda, Maryland 20205

Telephone: 301/496-6515

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA85-HL-27-HMOLECULAR CHARACTERIZATION OF ION CHANNELS IN THE MYOCARDIAL SARCOLEMMA

P.T. 34; K.W. 1002004, 0710050, 1002059, 0785025, 1013004, 0765015

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: December 16, 1985

The Cardiac Functions Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject.

This program will support fundamental research on the structure, function, and regulation of ion channels in the myocardial sarcolemma at the molecular level. The major purpose of this special grant program is to encourage the application of modern cellular and molecular technologies, along with recent advances in electrophysiological techniques, in an effort to isolate and determine the molecular structure of ion channels, to correlate ion channel structure with physiological function, and to elucidate the regulatory processes governing ion channel activity. The Division of Heart and Vascular Diseases anticipates that approximately 6-8 grants will be awarded under this RFA program.

This announcement may be of particular interest to investigators in disciplines which include biochemistry, biophysics, cardiology, cellular biology, developmental biology, electrophysiology, genetics, molecular biology, and morphology.

TIMETABLE

Letter of Intent	August 15, 1985
Application Receipt Date	December 16, 1985
Technical Review	March 1986
Advisory Council Review	May 22-23, 1986
Award Date	June 1986

INQUIRIES

Inquiries concerning this program and requests for copies of the RFA should be addressed to:

Stephen C. Mockrin, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 304
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1627

ANNOUNCEMENTAVAILABILITY OF REQUEST FOR APPLICATIONS: RFA85-HL-28-LALPHA-1-PROTEINASE INHIBITOR DEFICIENCY AND EMPHYSEMA - MOLECULAR STUDIES

P.T. 34; K.W. 0760035, 0715165, 0765010, 0765015

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: December 16, 1985

The Division of Lung Diseases invites grant applications for a single competition for support of research on synthesis and secretion of alpha-1-proteinase inhibitor (A1-Pi, also known as alpha-1-antitrypsin) which is believed to provide protection for the lung against proteolytic breakdown, thereby preventing the development of emphysema. The long term goal of this program is to generate information that will provide a basis for attempts to increase the level of this protein in PiZZ individuals through pharmacologic manipulation or gene therapy. The specific objectives of this RFA program are to elucidate the mechanisms of regulation of transcription and translation of the A1-Pi gene, the post-translational modification as well as secretion and turnover of the protein in PiZZ individuals, and to compare these processes to those in individuals with normal levels of the antiprotease. The Division of Lung Diseases anticipates that approximately 6-8 grants will be awarded under this RFA program.

Inquiries regarding this announcement may be directed to the program administrator:

Zakir H. Bengali, Ph.D.
Airways Diseases Branch
Division of Lung Diseases, NHLBI
National Institutes of Health
Westwood Building - Room 6A15
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: 301/496-7332

ANNOUNCEMENT

ADDENDUM TO NIH GUIDE FOR GRANTS AND CONTRACTS - VOL. 14, NO. 5, APRIL 26, 1985

MINORITY INSTITUTIONAL RESEARCH TRAINING PROGRAM

P.T.44, FF; K.W. 0720005, 0715040, 0715165, 0785070

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: August 15, 1985

THE PURPOSE OF THIS ADDENDUM IS TO EXTEND ELIGIBILITY TO MINORITY HEALTH PROFESSIONAL SCHOOLS AND MINORITY POSTGRADUATE SCHOOLS.

The National Heart, Lung and Blood Institute (NHLBI) announces a program to support full time research training for investigative careers at minority schools in areas related to cardiovascular, pulmonary or hematologic diseases. Minority schools seeking this support must have: (1) graduate students, or; (2) health professional students who will take a minimum of one year from professional training, or; (3) postdoctoral students. The support mechanism will be the National Institutes of Health (NIH) institutional research training grant. Copies of the program guidelines are currently available from staff of the NHLBI, listed below.

Grants in this program will be made to minority institutions, each of which will cooperate with a research center that has a well-established cardiovascular, pulmonary, or hematologic research and research training program. Each trainee will be placed with a mentor who is an accomplished investigator at the cooperating research center and who will assist the advisor at the minority institution in the trainee's development and research plan. Guidelines for this program may be obtained from any of the following:

George A. Hayden, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A10
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Joan M. Wolle, Ph.D.
Division of Lung Diseases
National Heart, Lung, and
and Blood Institute
Westwood Building - Room 6A12A
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Luis Barbosa, D.V.M.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5C06
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1537

ANNOUNCEMENT

PREVENTION RESEARCH ON MUTUAL SUPPORT APPROACHES WITH BEREAVED POPULATIONS

MH-86-05

P.T. 34; K.W. 0745055, 0715195, 0403004, 0795005, 0411005, 0715070

NATIONAL INSTITUTE OF MENTAL HEALTH

The National Institute of Mental Health (NIMH) seeks applications for research on intervention with bereaved individuals and families through a mutual support approach.

I. SPECIFIC AREAS OF RESEARCH INTEREST

Areas of specific research interest under this announcement are:

- o The characteristics of different mutual support interventions and their ability to prevent negative health and mental health consequences, reduce psychological distress, and also promote social and emotional functioning.
- o The characteristics of individuals who seek or make use of mutual support interventions and the relationship of those characteristics to outcomes.
- o Controlled experiments of the development, implementation, outcome, and evaluation of new mutual support programs with bereaved persons.
- o The empirical testing with controlled research designs of existing mutual support programs for bereaved persons.
- o The comparison of members' characteristics, processes, and outcomes of specifically created mutual support programs with existing naturally occurring mutual support programs.
- o The comparison of mutual support interventions with psychotherapeutic and/or pharmacological interventions.
- o The differential effect of mutual support interventions designed for various phases and aspects of the bereavement process, e.g., anticipatory grieving, immediate distress, longer term social adaptation.
- o The refinement of methodologies for preventive intervention research for studying naturally occurring support, such as mutual support groups.
- o The refinement of existing measurement instruments to assess different aspects of support.
- o Empirical studies of bereaved individuals or groups for whom there are few research findings, e.g., community samples of bereaved children, non-Caucasian and non-middle class samples, adults who lose a parent or sibling, family units, survivors of suicide.

- o Research which follows up subjects for at least two years.
- o Research comparing bereavement with other life stressors.
- o Research documenting and refining risk factors for poor outcome following bereavement in preparation for designing interventions.
- o The differential impact of interventions on high- versus low-risk individuals.

II. APPLICATION CHARACTERISTICS

Applications submitted under this announcement should be based on hypotheses generated from basic research on both the grieving process and social support/mutual support, should focus on mutual support interventions with bereaved persons or families, and should also address:

- o Age, sex, socioeconomic status, ethnicity, and other relevant characteristics of subjects, e.g., relation to deceased, prior health and mental health status, and their relation to the intervention content and outcomes.
- o The nature of the death, e.g., accident, terminal illness, acute illness, suicide, violence.
- o The phase of bereavement to which the intervention is addressed.
- o An awareness of cultural diversity in reactions to bereavement.
- o Intervention content and goals.
- o Type of intervenor (professional, lay, religious) and relation to outcome.
- o Specification and justification of intervention outcomes and their measurement, e.g., behavioral, psychological, and social.
- o Comparison of self-report and objectively measured outcomes.
- o Linking of outcomes to be assessed to intervention content and goals.
- o Possible iatrogenic effects of intervention.

III. PREAPPLICATION PROCEDURES

Potential applicants are encouraged to seek preapplication consultation from:

Anita Eichler, Project Officer
Bereavement Research Initiative
Center for Prevention Research
Division of Prevention and Special Mental
Health Programs, NIMH
Parklawn Building - Room 11C-06
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4283

IV. REVIEW PROCEDURES

Applications will be reviewed in accordance with the standard review procedures of the Public Health Service and in accordance with the usual NIMH receipt, review, and award schedule.

V. REVIEW CRITERIA

Criteria for review of applications will include:

- o Significance and originality from a scientific or technical standpoint of the goals of the proposed research.
- o Adequacy of scientific basis for the intervention.
- o Appropriateness and adequacy of the methodology to carry out the research.
- o Appropriateness of specificity of intervention content.
- o Appropriateness of design for collection and analysis of data.
- o Qualifications and experience of the principal investigator and proposed professional staff.
- o Reasonable availability of resources necessary for the research.
- o Reasonableness of the proposed budget and duration in relation to the proposed research.
- o Potential cost effectiveness, replicability, and generalizability for proposed intervention models.
- o Adequacy of provisions for the protection of human subjects.

VI. AWARD CRITERIA

Applications recommended for approval will be considered for funding on the basis of:

- o Scientific and technical merit, as determined by the peer review process.
- o Potential contribution to the areas identified in this announcement and balance among those areas.
- o Availability of funds.

VII. FURTHER INFORMATION

For further information, terms and conditions of support, and a copy of the complete announcement, applicants should contact Anita Eichler, Project Officer (see above).

ANNOUNCEMENTRESEARCH ON METHODS FOR STUDYING MENTAL HEALTH SERVICE SYSTEMSMH-86-06

P.T. 34; K.W. 0730050, 0408000, 0417000, 1010011, 0404020, 1010013

NATIONAL INSTITUTE OF MENTAL HEALTH

I. PURPOSE AND OBJECTIVES

This announcement is to encourage research directed toward the improvement of methods by which to conceptualize, identify, measure, characterize, analyze, and describe features of mental health service systems at local community, State, or national (including comparisons with other nations) levels.

All research projects supported under this announcement must develop generalizable knowledge. Since the ultimate goals of the National Institute of Mental Health (NIMH) are increased mental health, decreased mental illness, and more effective clinical and administrative practice, the methods to be developed must be applicable to clinical and administrative practice in mental health services. Priority will be given to projects which propose methods that are economical to use and apply to a range of important research issues and situations.

II. RESEARCH TOPICS

Areas in which research will be supported are:

- o The development, testing, and refinement of methods for identifying, assessing, and analyzing the pattern of relationships among mental health service organizations within a mental health service system (community, State, region, or Nation), and between mental health service organizations and other components of the mental health service system (e.g., other types of service providers, those who need and/or seek services, and service regulators).
- o The development, testing, and refinement of theories, concepts, and research methods for characterizing the structure, boundaries, and functioning of mental health service systems (derived from any of a variety of research disciplines, including, but not exclusively, organizational sociology, economics, applied history, operations research, mental health administration, mental health services research, and clinical fields).
- o The development, testing, and refinement of methods of assessing power, identifying control points, and characterizing decision-making within the mental health service system.
- o The development, testing, and refinement of system measures, as they influence the delivery of care, and the reciprocal impacts of such services on the general social, economic, and political environment, and on the mental health service system itself.

- o The development, testing, and refinement of simulation, modeling, and other operations research procedures to characterize the functioning of various mental health service systems.
- o The demonstration of ways to adapt existing methods of measuring service-system characteristics and customary procedures of recording program and service information to yield measures of use in comparative studies of service systems.
- o The development of procedures to answer statistical and logical problems of dealing with all the components of a system in aggregate (e.g., the ecological fallacy).

III. REVIEW

Applications will be reviewed in accordance with the usual Public Health Service peer review procedures. They will first be reviewed for scientific and technical merit by an initial review group (IRG) composed primarily of non-Federal scientific consultants. The results will be reviewed by the National Advisory Mental Health Council. Only applications recommended for approval by the Council will be considered for funding.

IV. REVIEW CRITERIA

In review of applications, the IRG will consider:

- o Clarity, specificity, and importance to the mental health field of project objectives.
- o Quality of project design and methodology as evidenced by a detailed research plan, including:
 - clear description of the proposed research
 - valuable, feasible, and reasoned aims for the study
 - cogent theory or practice relevant hypotheses to be tested
 - appropriate kinds of data to be obtained and appropriate means by which the data will be collected, analyzed, and interpreted
 - recognition of the limitations of the procedures proposed and reasonable plans to overcome possible pitfalls
 - realistic timetable for the accomplishment of the main steps in the project
- o Significance of the issue(s) and potential of the project for improving future research on the mental health service delivery system, scope of research topics, and situations to which the new or revised research methods will apply.
- o Appropriateness of the sponsorship and collaborative arrangements to the nature of the problem and potential use of results.

- o Evidence of cooperation and commitment from significant persons and organizations whose support will aid the accomplishment of the project and acceptance and use of its results.
- o Quality of the plan for disseminating results of the project to appropriate audiences in a manner that will facilitate the use of the information.

V. RECEIPT AND REVIEW SCHEDULE

<u>Receipt of Application</u>	<u>Initial Review</u>	<u>National Advisory Mental Health Council</u>	<u>Earliest Award Date</u>
Nov. 1, 1985	March 1986	May 1986	July 1986
March 1, 1986	June 1986	September 1986	December 1986
July 1, 1986	Oct. 1986	February 1987	April 1987

Thereafter, applications may be submitted as part of the regular grant cycle.

VI. AWARD CRITERIA

- o Quality of the proposed project as assessed during the review process.
- o Relationship of the project to the goals of the NIMH Service System Research Program, and the likelihood that, if funded, the project will contribute significantly to improving the quality, replicability, quantity or economy of future research on important problems on the mental health service system.
- o Speed with which study results will be available.
- o Balance among projects in terms of approaches used and phenomena to be measured, disciplinary perspectives employed, and types of application of methods.
- o Availability of funds.

VII. STAFF CONSULTATION

NIMH staff are available for consultation concerning proposal development in advance of or during the process of preparing an application. Potential applicants should contact NIMH as early as possible for information and guidance in initiating the application process. Inquiries regarding the relevance of potential projects to the broader Mental Health Service System Research Program or regarding the technical aspects of proposal submission, research design, and methodology should be directed to one of the following staff:

James W. Thompson, M.D., M.P.H., Chief
 Service System and Economics Research Branch
 Charles Windle, Ph.D., Chief
 Service System Research Program or
 Armand Checker, M.A., Research Statistician
 Service System Research Program

Division of Biometry and Epidemiology
Parklawn Building - Room 18C-03
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4233

For a copy of the complete announcement and further information, such as application characteristics, procedures, and terms and conditions of support, applicants should contact one of the staff listed above.

NOTICE

REVISED NIH GRANT POLICIES AND PROCEDURES

P.T. 34; K.W. 1014002

The six NIH grant policy and procedure issuances listed below represent recent revisions and are reprinted on the pages which follow:

- 4209 - Cost Sharing in Research Grants
- 4805 - Research Grants Awarded to Non-Affiliated Individuals
- 4811 - Notification and Treatment of Released Funds Resulting From Issuance of a Research or Academic Career Award
- 4820 - Establishing and Operating Consortium Grants
- 5002 - Notice of Disposition of Grant Unexpended Balance
- 5806 - Overdue Reports - Discretionary Grants

(See Attached)

4209 - COST SHARING IN RESEARCH GRANTS

- A. Purpose This issuance revises the NIH policy concerning cost sharing requirements applicable to research project grants, and provides guidance in the negotiation of project-by-project cost sharing agreements as applicable for NIH research grants. It implements PHS Grants Administration Manual Chapter 2-140 and 1-400, and supersedes other instructions inconsistent with the present policy and instructions.
- B. Applicability This policy is applicable to all research projects supported by NIH grants except those awarded to other Federal agencies which are exempted from the requirement of cost sharing.
- C. References
1. PHS Grants Administration Manual Chapter 2-140, Cost Sharing in Research Grants
 2. PHS Grants Administration Manual Chapter 1-400, Matching and Cost Sharing
 3. DHHS Publication No. OS 75-50009, A Guide to Institutional Cost Sharing Agreements for Research Grants and Contracts Supported by the DHHS
 4. 45 CFR, Part 74, Subpart G, Cost Sharing or Matching
 5. NIH Manual Chapter 5601, Disposition of Grant Related Income
 6. NIH Manual Chapter 4820, Guidelines for Establishing and Operating Consortium Grants
- D. Definitions
1. Competitive Segment The initial period of recommended support (1 to 5 years) or each successive competing continuation period of a project period.
 2. Cost Sharing A cost participation requirement, included in the Department of Health and Human Services' annual appropriation acts, stating that HHS funds cannot pay for the entire cost of a research project. Cost sharing is a contribution by the grantee which may be in cash, in kind, or both, derived from either the grantee institution or from third party institutions, organizations, or individuals.

4209 - COST SHARING IN RESEARCH GRANTS

- E. Policy Cost sharing shall be required on every NIH grant-supported research project except those awarded to other Federal agencies. Non-profit grantee institutions may share in the costs of grant-supported research either through an institutional agreement covering the aggregate of all PHS research grants subject to cost sharing or by separate agreements for each research project (project-by-project basis). For profit organizations must cost share under the latter method.

Cost sharing requirements on foreign grants, grants to individuals, and, usually, conference grants are met through nonpayment of indirect costs.

- F. Responsibility DHHS has delegated responsibility for cost sharing administration as follows:

1. The Public Health Service is responsible for negotiating and administering institutional cost sharing agreements on behalf of all DHHS agencies. The PHS shall provide the operating agencies with current listings of all institutions having a cost sharing agreement, indicating the types of agreements and the effective dates. Grantee institutions submitting institutional cost sharing proposals should direct them to:

Chief, Cost and Audit Management Branch
Division of Grants and Contracts
Public Health Service
Parklawn Building, Room 18A30
5600 Fishers Lane
Rockville, Maryland 20857
Telephone: (301) 443-3080

NIH awarding units needing information concerning institutional cost sharing agreements should contact the following NIH office which has liaison responsibility with the PHS office identified under F.1.

Grants Policy Office
Office of Extramural Research and Training
Building 31, Room 1B58
Telephone: 496-5967

2. The NIH awarding units are responsible for:
 - a. Ascertaining prior to award whether the proposed grant is covered by an institutional cost sharing agreement as shown on the list provided by PHS, and, if so, to indicate on awards that an institutional agreement is in effect, and to cite the effective date of the agreement.

4209 - COST SHARING IN RESEARCH GRANTS

- b. The negotiation and administration of an individual project cost sharing agreement in the absence of an institutional agreement for non-profit grantees and in all cases for for-profit grantee organizations.

G. Implementation

1. General Guidelines

As applicable, awarding units should encourage the use of institutional cost sharing plans covering all PHS research grants to non-profit institutions. Institutional plans (1) provide the most meaningful basis for showing the extent to which non-Federal funds contribute to the cost of research which is also supported from Department funds at a given institution, (2) give maximum flexibility to grantees as to the method used to meet the established cost sharing level, and (3) simplify administration of the research project application, review, negotiation, award and reporting procedures for both the institution and the awarding unit.

The amount of cost sharing may vary in accordance with a number of factors relating to the type of grantee organization and the character of the research effort. In the final analysis the amount of cost participation should reflect the mutual agreement of the parties, provided that it is consistent with any statutory requirements.

For specific guidance on extent of cost sharing and valuation of in-kind contributions from third parties see PHS Grants Administration Manual Chapters 2-140 and 1-400.

2. Project-by-Project Cost Sharing Agreements

In the absence of an institutional cost sharing agreement and in all cases involving for-profit grantees, project-by-project agreements will be negotiated and administered by the NIH awarding unit within the following guidelines:

- a. The awarding unit shall request the applicant institution to submit an individual cost sharing proposal for each competitive segment (1 to 5 years) at the time it is notified that a project will be funded. A suggested format containing the information required is attached (see Illustration I).

4209 - COST SHARING IN RESEARCH GRANTS

- b. The proposal will cover the entire competitive segment and will state the minimum percentage of total allowable project costs (i.e., the combined Federal and grantee shares) which the applicant proposes to contribute to the planned research. A proposal of less than 5% of non-Federal costs contribution for each competitive segment requires justification by the applicant and approval by the awarding unit's Grants Management Officer. The grant may not be awarded until the applicant and the awarding unit have agreed to a cost sharing percentage. This percentage shall be specified on the Notice of Grant Award to signify the awarding unit's acceptance of the applicant's proposal.
- c. There may be no contribution, or only a token contribution, in some years of the competitive segment provided that the agreed overall percentage for the project as a whole is met. Separate cost sharing proposals will not be required for subsequent noncompeting continuations and supplements of the same competitive segment. If there is an early termination of the project, the negotiated cost sharing percentage will apply to the actual abbreviated period of Federal support.
- d. The grantee contribution must be project-related and may be from any non-Federal source except for those made by a Veterans Administration hospital participating with the grantee in a project. Grantees will not be required to obtain prior awarding unit approval of the budget categories in which costs are to be contributed. The contribution may be in any allowable budget category or combination of categories such as salaries, equipment, supplies, travel, or indirect costs.
- e. Expenditure of the Federal share of grant-related income will not be allowed to meet cost sharing agreements except for grants under those programs where it is clear that legislative intent was to permit such income to be used for that purpose.
- f. Grantee institutions should not submit individual cost sharing proposals until notified by the NIH awarding unit that an application has been approved and that a cost sharing agreement is required.

4209 - COST SHARING IN RESEARCH GRANTS

- g. At the termination of each competitive segment, the awarding unit will verify the amount of cost sharing reported against the percentage agreed to at the initiation of the competitive segment. If the cost sharing percentage is less than that agreed to but still 5% or greater, the awarding unit shall review the contributing factors and make the determination as to its acceptability. If the cost sharing percentage is less than that agreed to and also less than 5%, a detailed explanation and justification should be requested from the grantee institution and the matter then referred to the awarding unit Grants Management Officer for resolution.
- h. Cost sharing agreements may be amended retroactively for a lower contribution to avoid unanticipated hardship on grantee institutions; however, this should be permitted only rarely.
- i. An amended agreement must be submitted anytime there is a name change or when the structure of the institution is changed through merger, successor in interest agreement or any other means.

3. Agreements With Cooperating Institutions Under Consortium Grants

Grantee institutions are responsible to the NIH awarding unit for the entire non-Federal contribution to the total cost of the research project, either under an individual or institutional cost sharing agreement. Written agreements negotiated by the grantee with each cooperating institution(s) may include an arrangement whereby the cooperating institution will cost share in proportion to its participation in the total project.

4. Reporting Requirements and Documentation

Grantees are required to report cost sharing for each budget period on a Financial Status Report as follows:

- a. For institutional agreements, show "institutional, and the effective date" in the remarks block on the form.
- b. For project-by-project agreements, show the amount of the non-Federal cost sharing for the period covered by the Financial Status Report. If there was no cost sharing during the reported period, indicate "no c.s." on the appropriate line of the form.

4209 - COST SHARING IN RESEARCH GRANTS

- c. If the grantee wishes to provide cost sharing in the indirect cost category, it should reduce the claim for indirect cost to which it would otherwise be entitled, indicating the total amount and the Federal share on the Financial Status Report as appropriate. In this event, an explanation should be included in the "Remarks" section of the report, that the claim for less than allowable indirect cost is intentional.

5. Application Review Process

The extent of cost sharing proposed by applicants should not influence judgments on merit or relevance and may not be a factor in the competition for research grants. Application forms will not request information on cost sharing nor are individual cost sharing proposals to be solicited until peer review has been completed and funding is assured. No aspect of cost sharing may be made available to consultants engaged by the NIH to evaluate the merit of research grant applications.

H. Audit

Records showing the manner and source of non-Federal support must be made available to Federal auditors upon request.

I. Effective Date

This policy is effective immediately.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20205

Date _____ Recommended
Competitive Segment _____

Grant No. _____ Recommended
Direct Costs \$ _____

Principal Investigator _____ \$ _____

Title of Project _____ \$ _____

TO : _____ \$ _____

FROM: _____ \$ _____

SUBJECT: Project-by-Project Cost Sharing in Research Grants

In keeping with the public Health Service policy on cost sharing in research grants, it is necessary to establish in advance of an award the extent of cost participation by the applicant institution. In the absence of an institutional cost sharing agreement with the PHS, a separate proposal will be required for each research project to be supported by an NIH grant.

Please provide the information required for project-by-project cost sharing as indicated below for the subject research project, which has been recommended for approval for the competitive segment indicated and in amounts not to exceed those shown for direct costs to which related indirect cost at a rate not to exceed that accepted by DHHS may be added.

In presenting the needed data, it is important to note (1) that the cost sharing percentage proposed applies to the total competitive segment rather than to annual budget periods, (2) total allowable costs of the project include both costs charged to the Federal grant funds and costs contributed by the grant organization, and will be determined in accordance with the cost principles designated by the granting agency, and (3) that any proposed contribution of less than five percent of the total allowable project costs must be accompanied by a detailed explanation and justification of the reason therefor.

Information Required for Project-by-Project Cost Sharing

_____ proposes to share in the costs of Grant
(Name of Applicant Organization)

No. _____ during the competitive segment _____ (of any
(Inclusive Dates)

subsequent revision of that competitive segment to the minimum extent of _____ percent of the total allowable costs of the project. It is understood if the competitive segment consists of more than one budget period, this minimum percentage will apply to the competitive segment as a whole but not necessarily to each budget period equally.

Signature and Title of Authorized Grantee Official

Date

4805 - RESEARCH GRANTS AWARDED TO NON-AFFILIATED INDIVIDUALS

- A. Purpose This issuance sets forth the policy which applies to research grants awarded to non-affiliated individuals as grantees rather than to an institution or organization.
- B. Applicability This policy is applicable to NIH research project grants.
- C. References
1. NIH Manual Chapter 4209, Cost Sharing in Research Grants
 2. NIH Manual Chapter 5202, Prior Approval of Use of NIH Grant Funds Including Rebudgeting
 3. NIH Manual Chapter 5602, Management of and Accountability for Equipment Acquired Under NIH Grants
- D. Policy In exceptional cases, a research project grant may be made to a non-affiliated individual in the United States rather than to an institution or organization. In such cases, special administrative features pertain (see E. Implementation below).
- E. Implementation
1. Allowances and Expenditures No indirect cost allowance will be provided to individuals as grantees; nor may they use grant funds for alterations or renovations, or for the purchase of fixed equipment. Otherwise, the expenditures policies applicable to research grants made to grantee institutions and organizations are applicable to grants made to individuals.
 2. Human and Animal Subject Research In accordance with Department of Health and Human Services Regulations, 45 CFR 46, and the Public Health Service Animal Welfare Policy, 1-43, no individual may receive NIH grant funds for non-exempt human subjects research or animal research unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under a written Assurance of Compliance or the individual makes other arrangements with the Department. For information concerning human subjects and/or animal assurances and related arrangements, contact the Office for Protection From Research Risks, Building 31, Room 4B09. Telephone: 496-7005.
 3. Cost Sharing The non-payment of indirect costs on grants to individuals satisfies cost sharing requirements.

4805 - RESEARCH GRANTS AWARDED TO NON-AFFILIATED INDIVIDUALS

4. Equipment Title to equipment acquired by an individual as a grantee shall vest upon acquisition in the Federal Government with final disposition to be determined by the awarding unit upon termination of the project.
5. Payment of Grants Funds Individuals as grantees may obtain an advance of funds on a monthly basis in the amount of estimated disbursements to be made during a month, or on a reimbursable basis, by writing a letter identifying their grant number and cash requirements to:

Accounting and Indirect Cost Section
Federal Assistance Accounting Branch
Division of Financial Management
National Institutes of Health
Building 31, Room B1B04
9000 Rockville Pike
Bethesda, Maryland 20205
6. Prior Approval Authority Individuals as grantees must obtain prior approval from the Grants Management Officer of the NIH awarding unit for all proposed programmatic changes and rebudgeting actions for which prior approval is required.
7. Reporting The individual as a grantee has the same reporting requirements as a grantee institution or organization.
- F. Responsibility Although the individual is held entirely responsible for the grant, personal indemnity bonds are not required. The awarding unit Grants Management Officer and designated program official are jointly responsible for regular contact with the grantee individual to ensure that the terms of the grant are being met.
- G. Effective Date This policy is effective immediately.

4811 - NOTIFICATION AND TREATMENT OF RELEASED FUNDS
RESULTING FROM ISSUANCE OF A RESEARCH OR
ACADEMIC CAREER AWARD

Page 1

- A. Purpose. This issuance sets forth the notification and adjustment procedure to be followed by all NIH bureaus, institutes, and divisions (BIDs) in the timely identification and treatment of grant funds budgeted for an individual's salary and applicable fringe benefits, but freed as a result of funding an NIH research or academic career award.
- B. Background. Since 1962, NIH has had a policy that grantee institutions may not automatically retain grant funds freed as a result of providing salary and applicable fringe benefits for an individual through an NIH research or academic career award and use them for other project-related purposes. Grantee institutions are required to seek prior approval from awarding units in order to retain such funds. Inasmuch as the current PHS Grants Administration Manual Chapters and the PHS Grants Policy Statement do not include detailed procedural guidelines or indicate under what circumstances it may be appropriate to allow the retention of such funds, it is intended that this document will guide NIH staff in carrying out this responsibility.
- C. Applicability. This policy is applicable to NIH research or academic career awards (application prefix code K) and affected NIH research and training grants.
- D. Policy. Funds budgeted in an NIH-supported research or training grant for an individual's salary and applicable fringe benefits, but freed as a result of funding a research or academic career award for that individual may not be used for any other purpose except when the career award recipient no longer participates in the grant-supported activity and another individual replaces him/her and requires comparable remuneration. Only under some highly unusual circumstance should consideration be given to approval for use of released funds for any other reason than the one described above. In any event, the proposed retention and utilization of funds released in this manner must receive prior written approval of the awarding unit.
- E. Implementation and Responsibility.
1. Prior to issuing a research or academic career award, awarding unit staff shall seek and receive in writing from the prospective grantee institution the following:

4811 - NOTIFICATION AND TREATMENT OF RELEASED FUNDS
RESULTING FROM ISSUANCE OF A RESEARCH OR
ACADEMIC CAREER AWARD

- a. Information about all current or pending salary and applicable fringe benefit support being provided by Federal funds to the proposed awardee;
- b. Identity of awarding agency or unit, grant or award number, grant or award period, and annual support amount; or
- c. A negative report that no such support is current or pending, if such is the case.

In soliciting such information, the awarding unit should restate the NIH policy concerning the treatment of freed funds as a result of funding a research or academic career award. (See D. above.)

An example of a format for obtaining the above information is included as Illustration 1.

2. After receiving the required information, the awarding unit grants management staff is responsible for immediately sending written notification to all other NIH BIDs, other PHS awarding units, and other Federal agencies which have been identified as providing current salary and applicable fringe benefit support to the prospective research career or academic awardee that such an award will be made by the NIH. The BID should also provide a copy of the letter notifying the applicant that the research or academic career award is to be made. This notification system alerting all identified current or potential awarding units should enable each to promptly determine the disposition of freed Federal funds in accordance with the requirement of this policy. For other than NIH awarding units, final determination concerning disposition is entirely at the discretion of that component. For NIH awarding units, the determination shall be made under the policy stated in D. above.
3. An NIH BID receiving notice that a grant awarded by them will contain released salary and applicable fringe benefit support shall act promptly to either approve the use of the released funds or to restrict or recover them in accordance with the policy provisions of D. above. Any adjustment to an active or pending grant must include consideration of the future years of recommended support as well as the current year.

4811 - NOTIFICATION AND TREATMENT OF RELEASED FUNDS
RESULTING FROM ISSUANCE OF A RESEARCH OR
ACADEMIC CAREER AWARD

4811

Page 3

F. Effective Date. This policy is effective immediately.

4811 NOTIFICATION AND TREATMENT OF RELEASED FUNDS RESULTING
FROM ISSUANCE OF A RESEARCH OR ACADEMIC CAREER AWARD

Sample Format for Information Requested From
Prospective Research and Academic Career Awardees

(NIH AWARDING UNIT)

RESEARCH AND ACADEMIC CAREER AWARD PROGRAMS

REPORT OF CURRENT SALARY SUPPORT FROM FEDERAL
FUNDS AND PENDING APPLICATIONS FOR FEDERAL
SUPPORT

IDENTIFYING NUMBER

NAME OF AWARDEE

NAME OF SPONSORING INSTITUTION

SALARY RECOMMENDED

This is to inform you that an application for a Research or Academic Career Award has been approved in behalf of the above named individual. Any other Federal grant or contract award which provides salary and/or fringe benefit support for the anticipated Awardee will, therefore, no longer be required for that purpose. Funds thus released from other National Institutes of Health support mechanisms may not be retained by the recipient institution for any purpose, except when the award recipient no longer participates in the grant program(s) and another individual replaces him/her and requires comparable remuneration. Only for some highly unusual or special circumstance may prior approval be given for retaining released funds for any other reason than the one described above.

Please complete this form indicating all current or pending salary and/or fringe benefit support provided by Federal funds for the above named Awardee. Identify all pending support by "(P)" in the Grant or Award Number column below. Since it is not possible to issue this award until the completed form is received, please return the form promptly to the address shown below:

NIH AWARDING UNIT OR OTHER FEDERAL AGENCY	GRANT OR AWARD NUMBER	GRANT OR AWARD PERIOD	AMOUNT OF ANNUAL SALARY AND FRINGE BENEFITS AUTHORIZED

If no other Federal funds contribute to the salary and/or fringe benefit support of the awardee, or if no application or proposal for such support is pending, check here: ☒

INDICATE REQUESTED ACTIVATION DATE: _____

SIGNATURES

AWARDEE _____ DATE _____ DEPARTMENT CHAIRMAN OR SPONSOR _____ DATE _____

OFFICIAL AUTHORIZED TO SIGN FOR INSTITUTION _____ DATE _____

4820 - ESTABLISHING AND OPERATING
CONSORTIUM GRANTS

- A. Purpose This issuance revises policy for the establishment and operation of a consortium grant with a sound administrative base among the participating institutions and between the NIH awarding unit and the grantee institution.
- B. Background In the 1970s, NIH began to receive research grant applications in which support was sought for a single project involving multiple institutions. The inter-institutional administrative and programmatic arrangements were reflected by various types of collaborative agreements - some adequately serving their purposes and some not. As the need for, and interest in, the consortium type of grant grew, NIH began to receive an increasing number of consortium grant applications reflecting the involvement of a greater number of collaborating institutions applying their talents to an increasing portion of the research endeavors. Thus, this policy has evolved from experience with the first consortium grant and has been developed through cooperative efforts of grantee institutions and the NIH in recognition of the special needs of these particular grants.
- C. Applicability This policy is applicable to any NIH grant-supported research project which embodies the characteristics of the consortium grant as defined below.
- D. Definition A consortium grant is defined as: A grant to one institution in support of a research project in which any programmatic activity is carried out through a collaborative arrangement between or among the grantee institution and one or more other institutions or organizations which are separate legal entities, administratively independent of the grantee. The involvement of the non-grantee (collaborating) institution is that of actually performing a portion of the programmatic activity as opposed to simply providing a routine service to the grantee such as equipment fabrication or repair, data processing, or performing routine analytical testing services.
- E. Policy
1. The NIH may make an award for the support of a project to a grantee institution on behalf of a named principal investigator or program director even though one or more institutions other than the grantee are collaborating in the project by carrying out portions of the planned program activity. A proper certification reflecting inter-institutional understanding and basic agreement must be developed between the grantee and each individual collaborating institution.

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2. To be eligible for the award of such a grant, the grantee institution must ensure that it will, in fact, perform a substantive role in the conduct of the planned research project activities and not be primarily a conduit for the transmission of funds to another party or multiple parties. In general it is expected that a significant portion of the research activity will be carried out at the grantee institution.
3. Consortium arrangements which have not been proposed and documented in a grant application may not be entered into after a grant award has been made without the specific written prior approval of the awarding unit.
4. Only the grantee institution will receive entitlement credit for a Biomedical Research Support Grant. No proration of entitlement to other consortium institutions is allowed.

F. Conditions of Application and Award

1. Agreement prior to application submission. Prior to submission of an application for a consortium grant the applicant institution and each collaborating institution should thoroughly explore and reach at least tentative agreement on the scientific, administrative, financial, and reporting requirements for the grant.
2. Application preparation. The application form for consortium grants is the same form used for other NIH research proposals (form PHS 398). For consortium arrangements the application must include the following additional information:
 - a. A list of all proposed performance sites both at the applicant institution and at the collaborating institutions.
 - b. A separate, detailed budget for the initial and future years for each institution and, where appropriate, for each unit of activity at each institution.
 - c. A composite budget for all units of activity at each institution for each year, as shown under b. above, as well as a composite budget for the total proposed budget for each year.
 - d. An explanation of the programmatic, fiscal, and administrative arrangements made between the grantee institution and the collaborating institutions.

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CONSORTIUM GRANTS

- e. The following statement, accompanied by signatures of the appropriate administrative officials from each of the collaborating institutions, must be included as part of the application:

"The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the NIH consortium grant policy and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy."

3. Written agreement. The grantee institution must formalize in writing the agreement negotiated with each collaborating institution. The agreement must state the programmatic, fiscal, and administrative arrangement ensuring the compliance with all pertinent Federal regulations and policies and facilitating a smoothly functioning collaborative venture. Based upon the amount of information pertaining to the written agreement(s) which might be provided with the application, the awarding unit may determine that it is necessary to obtain more specifically detailed information from the grantee institution. The grantee can comply with such a requirement either by submitting copies of the actual written agreement(s) or by providing similarly clarifying information in some other format. Generally such information, needed for administrative review as to completeness will be required prior to the time of grant award statement issuance. Any review and acceptance by the awarding unit of the information provided does not constitute a legal endorsement of the written agreement(s) by the Federal Government. Nor does such acceptance establish NIH as a party to any of the agreement provisions. When requested, if it is not possible for the grantee institution to provide the NIH awarding unit with the additional documentation prior to award, it may be necessary to impose appropriate award restrictions, pending receipt and acceptance of the material.

As a general rule it should not be necessary to request detailed information concerning the written agreement during noncompetitive continuation application review unless the relationship between the grantee institution and its collaborating institution(s) is going to be significantly modified in any of the programmatic, fiscal, or administrative aspects. Accordingly, it is the responsibility of the grantee to provide an explanation of any significant proposed modification of the written agreement(s) in the continuation application or by letter if the decision on a change is made after application submission. Based on the type of explanation provided, the awarding unit will make a determination as to the possible need for more information to facilitate its

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review. As in the above paragraph, the grantee when asked for more details on the approach taken in the agreement(s) would have the option of submitting copies of the actual agreement(s) or presenting similar information in some other format.

- a. Programmatic considerations. The agreement must identify the principal investigator and the responsible persons at each collaborating institution and describe their responsibilities in the project. Procedures for directing and monitoring the research effort must also be delineated.
 - b. Fiscal considerations. The agreement must cite specific procedures to be followed in reimbursing each collaborating institution for its effort and must include dollar ceiling, method and schedule of reimbursement, type of supporting documents required for reimbursement, and procedures for review and approval of expenditure of grant funds at each institution.
 - c. Administrative considerations. Where policies of the collaborating institution differ from those of the grantee institution, (e.g. travel, travel reimbursement, salaries and fringe benefits) a determination should be made and included in the agreement as to which policies will be applied. Usually the policies of the institution where the costs are generated are applied to those costs, provided any such policies are in compliance with those of NIH.
4. Assurances required by NIH. The grantee institution has the specific responsibility for ensuring that all required assurances are obtained. The written agreement between the grantee institution and each collaborating institution must reflect the intent to fulfill all the requirements of the NIH and incorporate an understanding concerning at least the applicable assurances listed below:
- a. Protection of Human Subjects. Title 45, Code of Federal Regulations, Part 46 (45 CFR 46) requires that grantee institutions and collaborating institutions, when conducting some or all of the research involving human subjects, must have on file with or must submit to HHS upon request an Assurance of Compliance, approved in accordance with the regulations, setting forth the institutional policies and procedures established for the protection of human research subjects. Further information on the requirements of 45 CFR 46 may be obtained from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20205.

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- b. Care and treatment of laboratory animals In accord with PHS Grants Administration Manual Chapter 1-43 each grantee or collaborating institution receiving funds for research involving live, vertebrate animals must have on file with or submit upon request to PHS an Animal Welfare Assurance. The Assurance document commits the institution to comply with the Animal Welfare Act (P.L. 89-544, as amended) and the Guide for the Care and Use of Laboratory Animals (NIH Publication No. 80-23, Rev. 1978, or succeeding editions). Further information may be obtained from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20205.
- c. Non-Discrimination. Each domestic collaborating institution or organization must comply with Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, as amended (Handicapped Individuals). The grantee must ensure that all collaborating institutions have on file with the HHS Office for Civil Rights, valid Assurances of Compliance with the Civil Rights Act of 1964 (Form HHS 441) and Section 504 of the Rehabilitation Act of 1973, as amended (Form HHS 641).
- d. Patents and inventions. The fact that two or more institutions share in the grant-supported project does not alter the grantee institution's responsibilities concerning patents and inventions. The grantee institution should obtain appropriate patent agreements to fulfill the requirements from all persons who perform any part of the work under the grant and may be reasonably expected to make inventions. The grantee should insert into each such written agreement a clause making the patent and inventions policy applicable to each collaborating institution and its employees. Agreements should also be obtained by the grantee to govern disposition of rights to inventions resulting from screening compounds synthesized under the grant.
- e. Student unrest provisions. Each collaborating institution will be responsible for carrying out the provisions relating to remuneration from grant funds to any individual who has been engaged or involved in activities described as "student unrest." (General Provisions of the DHHS Appropriations Act each year since FY 1970.)

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- f. Recombinant DNA Research. The grantee institution, the collaborating institutions, and their respective principal investigators should refer to the most recent guidance from NIH concerning recombinant DNA research to determine the requirements necessary for the preparation of applications involving recombinant DNA experiments.
- g. Other. Any other assurance normally required of the grantee institution for the program in question is also required of the collaborating institutions.

G. Eligible Costs

- 1. Direct Costs. In general, any item of cost that is allowable under NIH policy for research grants may be requested in the application on behalf of both the grantee and collaborating institution(s). The expenditures are to be made in accordance with the NIH policies generally applicable to research grants. The requests for costs such as foreign travel, alterations and renovations, and research patient care must be accompanied by special justification.

It should be noted that no collaborating institution or organization which otherwise meets the eligibility criteria for receiving NIH grants in its own right can be paid a fee (over and above allowable direct and indirect costs) from grant funds for its participation in the consortium arrangement.

- 2. Indirect costs. Indirect costs for the grantee institution will be awarded routinely through the NIH Indirect Cost Management System (ICMS) of the Federal Assistance Accounting Branch, Division of Financial Management.

If indirect costs for a collaborating institution are required from the grant, they must be requested on the application budget page as a direct cost. The amount to be requested is determined by applying the DHHS-negotiated indirect cost rate for the collaborating institution to the appropriate direct cost base being requested for that institution. In such cases, the indirect cost amounts requested for collaborating institutions should be viewed as fixed maximum amounts for each year. The amounts requested for a collaborating institution's indirect costs for future years should reflect anticipated increases or decreases in indirect cost rates for the periods of requested support. That is, indirect cost rates used for collaborating institutions may vary - up or down - from the rate applicable at the time the competitive (new, renewal, or supplemental) application is submitted. Any such variance from already negotiated rates should, however, be accompanied by an explanation.

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While consortium arrangements may include the involvement of foreign institutions it should be noted that such institutions, whether serving as grantee or collaborator, cannot receive indirect costs.

H. Other Administrative Considerations

1. Rebudgeting authority of collaborating institutions. Rebudgeting between budget categories on the part of non-grantee collaborating institutions must have the prior approval of the grantee institution unless the grantee institution has established in the written agreement moderate levels of rebudgeting authority within PHS policy limitations with each of the collaborating institutions. In any case, the grantee institution must be responsible for assuring that the combined rebudgetings of both the grantee institution and collaborating institutions are consistent with PHS policy and that rebudgeting requests receive appropriate review (including those types of rebudgeting requests which require the review and prior approval of an awarding unit).
2. Audit guidelines. All costs incurred in the consortium grant will be subject to audit by the cognizant Federal audit agency. Upon request, cognizant Federal auditors will be provided access to records supporting grant-related costs of the collaborating institutions.
3. Cost sharing guidelines. The grantee institution is responsible to the NIH awarding unit for the entire non-Federal contribution to the total cost of the research project, under either an NIH individual (project-by-project) agreement or an institutional cost sharing agreement with the DHHS. In the event that the grantee is a for-profit organization, the project-by-project type of agreement must be utilized. The written agreement negotiated with each collaborating institution may include an arrangement whereby the collaborating institution will cost share in proportion to its participation in the total project. Any negotiated arrangement for multi-institutional cost sharing participation should be a part of the written agreement.
4. Equipment accountability and disposition. If the grantee is a non-profit organization, title to all equipment purchased with grant funds resides with the grantee. Further, if the grantee qualifies under a Federal statute as being exempt from further accountability to the Government for the equipment, the grantee may determine the disposition of the equipment at any appropriate

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time. Such a determination could enable the grantee to make arrangements as part of the written agreement for transfer of equipment items to the collaborating organizations early in the project (perhaps at time of acquisition) or as late as the time of project termination.

If the grantee is a for-profit entity, title to all equipment purchased with grant funds is retained by the Federal Government. Disposition of such Government-owned equipment will be determined by the awarding unit at the time of project termination.

5. Grant related income. The written agreement should establish the understanding that the grantee institution is accountable to the NIH for all grant related income generated by the grant supported activities. In accordance with PHS policy, the grantee is responsible for maintaining records of the receipt and disposition of grant related income in the same manner as required for the grant funds that gave rise to the income. The collaborating institution(s) will maintain records as necessary for the grantee institution to fulfill its responsibility.
6. Publications. The grantee institution and the collaborating institution(s) should have an initial, general agreement regarding authorship on research reports and other publications.
 - I. Reporting Requirements In order for the grantee institution to satisfy all of the various reporting requirements (e.g. progress report, report of expenditures, invention statement), it is necessary for each collaborating institution to provide the grantee with certain kinds of documentation. The written agreement must reference this need by stating the kinds of documentation required by the grantee as well as the timing of their submission.
 - J. Effective Date This policy is effective immediately.

5002 NOTICE OF DISPOSITION OF GRANT
UNEXPENDED BALANCE

- A. Purpose This issuance states the procedure for determining the disposition of an unexpended balance of authorization at the close of a competitive segment (see definition) of grant support and for notifying the grantee organization and the awarding component.
- B. Applicability All research and training grants (except fellowships) and cooperative agreements awarded by the National Institutes of Health.
- C. Background In 1970 the Notice of Disposition of Grant Unexpended Balance (NDGUB), form NIH 1686, was first introduced by the NIH as a means of notifying the grantee institution's business officer of the disposition of an unexpended balance following the receipt at the NIH of an expenditures report for a grant budget period. In 1971 the NDGUB was modified to conform to a revised procedure for making grant award adjustments related to estimated and actual unexpended and unobligated grant balances (see NIH Manual Issuance 5005). However, notwithstanding that modification, issuance of the NDGUB continued to be tied to individual budget periods within a "project period" (as the term was defined prior to 1979).

In 1979 the definition of a project period was significantly revised to consider competing continuations as extensions of the initially recommended project period. Thus, instead of considering each competing segment to be a separate and individual project period, it became possible to have project periods lasting five, ten, fifteen, or more years. This revision impacted on a number of grant administration procedures, including the use of the NDGUB. As indicated below (Section F, Procedure), the NDGUB is now used to notify the grantee organization's business office and the NIH awarding component of the action taken concerning the disposition of grant funds remaining at the end of each competitive segment.

D. References

1. NIH Manual Chapter 5005, "Grant Award Adjustments Related to the Estimated and Actual Unexpended and Unobligated Grant Balances."
2. Financial Status Report, Standard Form 269 (7-76).

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UNEXPENDED BALANCE

3. PHS Grants Administration Manual Chapter 1-85, "The Project Period System of Obligating Funds for Discretionary Project Grants."
4. NIH Guide for Grants and Contracts, Vol. 9, No. 2, January 25, 1980, Changes In The Project Period System For NIH Grants.
5. NIH Guide for Grants and Contracts, Vol. 9, No. 4, March 14, 1980, Changes In Project Period System For NIH Grants - A Clarification.

E. Definitions

Competitive Segment The initial period of recommended support (1 to 5 years) or each successive competing continuation period of a project period.

Budget Period The interval of time (usually 12 months) into which a multi-year period of assistance (project period) is divided for funding and reporting purposes.

Continuation An award which adds funds to support subsequent budget periods after the first. There are two basic kinds of continuations:

1. Noncompeting A continuation for a budget period that is within the approved competitive segment. These are noncompeting because they do not extend the existing project period by one or more budget periods.
2. Competing A continuation for a budget period that extends the currently established project period. These are competing because they add one or more budget periods to the existing project period.

Project Period The total time for which a project is approved for support, including any extensions thereof.

Final Expenditures Report A final Financial Status Report that must be submitted within 90 days of the completion of a grant, and must indicate the exact balance of unobligated funds and have no unliquidated obligations.

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Annual Expenditures Report A Financial Status Report that must be submitted for each budget period no later than 90 days after the close of such period. It indicates the financial status of a grant according to the official accounting records of the grantee organization and may include unliquidated obligations.

Unexpended Balance The portion of Federal funds authorized consisting of the unobligated balance of Federal funds plus the Federal share of unliquidated obligations, if any.

Unliquidated Obligations For Financial Status Reports prepared on a cash basis, the amount of obligations incurred by the grantee that has not been paid. For Reports prepared on an accrual basis, the amount of obligations incurred by the grantee for which an outlay has not been recorded.

Unobligated Balance The portion of Federal funds authorized which has not been obligated by the grantee and is determined by deducting the grantee's cumulative obligations from the cumulative Federal funds authorized.

F. Procedure

1. Division of Financial Management (DFM)

- a. At the time the final or annual expenditures report is received, DFM will routinely take one of two actions concerning any unexpended balance shown on the report:
 - (1) If it is the terminal year of the project, the unexpended/unobligated balance will be withdrawn from the grantee organization. (If a competing continuation award has not been issued, DFM necessarily must assume that the report received for the last year of support of a competitive segment is for expenditures against the terminal year of the project. Should there be a hiatus of support, DFM will, upon receipt of the competing continuation award and certification of funds availability, restore to the grantee organization the balance previously withdrawn. An amended NDGUB will be processed and distributed according to F.1.b.(3) below.)

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- (2) If it is within an approved project period, but at the end of a competitive segment, the unexpended balance will be carried forward to the next competing continuation award.
- b. The grantee organization and the awarding component will be notified of the action by means of the NDGUB, form NIH 1686 (Illustration 1). The Financial Status Report (or equivalent expenditures report) and the NDGUB will be processed as follows:
 - (1) The expenditures report is received in DFM for processing.
 - (2) A processed copy is coded to the NIH IMPAC System maintained by the Statistics and Analysis Branch, DRG, to reflect the receipt of the report.
 - (3) DFM prepares original and two copies of the NDGUB and distributes the original to the grantee organization; one copy goes to the awarding component, together with the original of the expenditures report; and DFM retains one copy, along with a copy of the expenditures report.

2. Grantee Notification

The NDGUB informs the grantee organization of the specific transfer of an unexpended balance from one competitive segment to another, and contains the following general information:

"Expenditures for the competing continuation period are limited to the sum total of (a) the approved budget (direct costs), (b) liquidation of reported prior year obligations and (c) applicable indirect costs."

"When the amount transferred, together with the amount awarded for a continuation period, results in overfunding, THE EXCESS IS NOT AVAILABLE FOR EXPENDITURE. The excess, excluding any unliquidated obligations, may be used by the awarding component to partially fund succeeding budget periods within the project period."

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UNEXPENDED BALANCE

"On the other hand, if the grant is underfunded by \$250 or more, the awarding component will within 30 days issue a revised award notice or a supplemental award for the balance needed to meet the level of the current approved budget. For any underfunding of less than \$250, when the current budget will be adversely affected, a request for adjustment must be made in writing to the awarding component."

3. Awarding Component If the awarding component does not concur with the terms as shown on the individual NDGUB, DFM should be advised and a correction or adjustment made accordingly.

During a project period the awarding component may reduce the grant award but only by means of a revised Notice of Grant Award.

- G. Effective Date This procedure is effective immediately.

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UNEXPENDED BALANCE

NIH Form 1686

NIH Manual 5002

<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH Bethesda, Maryland 20205</p> <p>NOTICE OF DISPOSITION OF GRANT UNEXPENDED BALANCE</p>	<p>DATE</p> <p>GRANT NO.</p>
<p>NAME OF GRANTEE ORGANIZATION</p>	<p>DOCUMENT NO.</p> <p>ORGANIZATION'S IO NO.</p> <p>ENTITY IDENTIFICATION NO.</p>

We have received the Financial Status Report or equivalent expenditures report submitted under the above grant. The unexpended balance of \$_____, which consists of the unobligated balance of Federal funds and the Federal share of unliquidated obligations, if any, has been processed as indicated below.

- ☐ Withdrawn from the reported grant project period.
- ☐ Transferred to the competing continuation award for the _____ year of support.

Grantees are reminded that expenditures for the competing continuation period are limited to the sum total of:

- (1) the approved budget (direct costs)
- (2) liquidation of reported prior year obligations and
- (3) applicable indirect costs.

When the amount transferred, together with the amount awarded for a continuation period, results in overfunding, THE EXCESS IS NOT AVAILABLE FOR EXPENDITURE. The excess, excluding any unliquidated obligations, may be used by the awarding component to partially fund succeeding budget periods within the project period.

On the other hand, if the grant is underfunded by \$250 or more, the awarding component will within 30 days, issue a revised award notice or a supplemental award for the balance needed to meet the level of the current approved budget. For any underfunding of less than \$250, when the current budget will be adversely affected, a request for adjustment must be made in writing to the awarding component.

Grants Section
Federal Assistance Accounting Branch
Division of Financial Management

5806 OVERDUE REPORTS -
DISCRETIONARY GRANTS

- A. Purpose This issuance states the guidelines for administrative action to be taken in assuring that grantees submit to NIH such reports as may be required as a condition of a grant award.
- B. Background A recurring problem in the administration of many NIH grant programs is the delinquency on the part of some grantees in submitting reports required as a condition of the grant award. These reports are divided into two general categories, identified as progress reports and management reports. Progress (performance) reports describe technical scientific accomplishments toward meeting project objectives. Management reports cover financial, administrative, or other non-technical (non-scientific) aspects of the grant-supported project.
- C. Applicability This issuance applies to all assistance programs (grants and cooperative agreements) in which the amount of the award and the decision to make the award are within the discretion of the NIH awarding unit.
- D. References
1. PHS Grants Administration Manual Chapter 1-42, Overdue Reports-Discretionary Grants
 2. NIH Manual Issuance 5805, Closeout of NIH Grants
 3. NIH Manual Issuance 5807, Submission and Acceptance of Revised Reports of Expenditures
 4. NIH Manual Issuance 5808, Establishment and Documentation of Files and Other Records, Including Monitoring Actions, for NIH Grant Programs
- E. Policy Each discretionary grant award is made subject to the condition that the grantee shall prepare certain technical progress reports and management reports and shall submit them on a predetermined basis to the appropriate unit at NIH. Awarding units shall take appropriate administrative action to assure the submission by grantees of required reports.
- F. Guidelines for Administrative Action The particular administrative action taken by the awarding unit will depend on the response, if any, received from the grantee to written requests for overdue required reports. The following procedures shall be followed by awarding units encountering a delinquent reporting situation:

5806 OVERDUE REPORTS -
DISCRETIONARY GRANTS

1. Delinquent Technical Progress Reports

When a grantee continues to be delinquent in submitting a required progress report or final report on the scientific and technical aspects of the grant (i.e., 30 days beyond the due date), the Grants Management Officer (GMO) of the awarding unit is responsible for the following actions:

- a. The GMO shall send a letter to the program director, principal investigator, or other person directly responsible for the report, notifying that person of the delinquency and requesting the report. The letter shall state that, if the report cannot be submitted promptly, the responsible individual should explain the reason and should state the date by which the awarding unit will receive the report.
- b. If neither the report nor an acceptable explanation for not submitting it is received within 30 days of the date of the first letter, the GMO shall promptly send a second letter. This letter shall be sent to the official of the grantee institution who is responsible for the administration of the grant notifying that official of the delinquency and of the prior attempt to obtain the required report. This letter may advise the grantee that failure to submit the report within 30 days could result in the awarding unit withholding any additional grants in which the principal investigator, or person responsible for the delinquent report, is involved until the overdue report is received.
- c. If neither the report nor an acceptable explanation for further delay is received within 30 days of the date of the second letter, the head of the grantee institution should be informed by letter from an awarding unit official at the Associate Director or Executive Officer level of the previous attempts to secure the required report. This letter may also state definitively that the awarding unit will not award any additional grants in which the program director, principal investigator, or person responsible for the delinquent report, is involved until the overdue report is received.
- d. If there is no acceptable response within 30 days of the above letter (it now being at least 120 days beyond the due date), the matter should be submitted to the Deputy Director for Extramural Research and Training (DDERT) with full documentation. (In the case of a final progress report, at least seven months have elapsed since the project ended.) The DDERT will determine alternative procedures which may be applied in order to try to obtain the missing report.

5806 OVERDUE REPORTS -
DISCRETIONARY GRANTS

2. Delinquent Management Reports

A delinquent management report is defined as: A management report which has not been received within seven months following expiration of the grant budget period it is to cover or, specifically with respect to a Financial Status Report (FSR), an FSR which has appeared on the Division of Financial Management (DFM) monthly delinquent report list for three months. (Under the DFM reporting schedule, FSRs that have appeared on the delinquent list three times are then roughly 4 months overdue or, in other words, approximately seven months have elapsed since the grant budget period ended.)

When, under the above definition, a grantee is delinquent in submitting a required management report, the GMO of the awarding unit is responsible for the following actions:

- a. The GMO shall send a letter to the grantee official responsible for the administration of the grant notifying that official of the delinquency and requesting submission of the report within 30 days of the date of the letter.
- b. If there is no reply within the 30 day period, the head of the grantee institution should be informed by letter from an awarding unit official at the Associate Director or Executive Officer level of the previous attempts (including the DFM delinquent report lists, if appropriate) to secure the required report. An acknowledgment of this letter within 2 weeks should be requested.
- c. Continued delinquency will result in the following actions:
 - (1) for active grants, no continuation award may be made if required reports have not been received.
 - (2) for both active and expired grants, if required reports have not been received prior to the normal anniversary date of the next grant (i.e., within a 12-month period), the case should be submitted to the DDERT with full documentation. The DDERT will determine alternative procedures which may be applied to try to obtain the missing reports.
- d. If a grantee institution is consistently delinquent on a general basis in the submission of required management reports, the situation will be called to the attention of the Division of Management Survey and Review, OA, NIH, for appropriate corrective action.



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DISCRETIONARY GRANTS

3. No Report Received - Waiver Procedure

In unusual cases, the GMO of the awarding unit may waive the requirement for a progress or management report or extend the date for submission when the grantee can satisfactorily demonstrate that it cannot furnish the report in a timely manner for reasons legitimately beyond its control or the purposes for which the report is to be used will be accomplished through other means. Grant files must be adequately documented to support the awarding unit's action.

G. Effective Date This policy is effective immediately.

NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 14, No. 8, June 25, 1985

SPECIAL EDITION

LABORATORY ANIMAL WELFARE

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

LOCATION OF DOCUMENTS

SPECIAL EDITION - NIH GUIDE FOR GRANTS AND CONTRACTS

Vol. 14, No.8, June 25, 1985

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INTRODUCTION

This Special Edition of the NIH Guide for Grants and Contracts contains four documents relevant to the care and use of laboratory animals:

- (1) The revised Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions. This policy revision represents several years of careful review and consideration of the PHS Extramural Animal Welfare Policy promulgated in 1979. A proposed draft of the policy was published for public comment in an April 5, 1984, Special Edition of the NIH Guide for Grants and Contracts. Approximately 340 comments on the proposal were received, both in writing and at three open hearings held during the summer of 1984 in Kansas City, Boston and Seattle. All of the comments were given careful consideration in the development of the revised PHS Policy.

The most significant changes in the revised policy are:

- a. The policy requires that each institution receiving PHS funds for research involving animals submit detailed information in an Animal Welfare Assurance regarding the institution's program for the care and use of animals.
- b. Awardee institutions will be required to identify an institutional official who is ultimately responsible for the institution's program for the care and use of animals, and a veterinarian qualified in laboratory animal medicine who will participate in the program. Institutions will also be required to designate clear lines of authority and responsibility for those involved in animal care and use in PHS-supported activities.
- c. The policy clearly defines the role and responsibilities of institutional animal care and use committees and will enhance the involvement of such committees in all aspects of PHS-supported research at institutions. The policy requires that institutional animal care and use committees include an individual unaffiliated with the institution, a veterinarian who has program responsibilities and who has training or experience in laboratory animal science and medicine, a practicing scientist experienced in research involving animals, and a member whose concerns are in a nonscientific area.
- d. The policy requires institutional animal care and use committees to review and approve those sections of applications for PHS funds that relate to the care and use of animals before PHS funds may be awarded.
- e. Institutions that are not accredited by the American Association for the Accreditation of Laboratory Animal Care will be required to conduct a self-assessment of the institution's program, based on the Guide for the Care and Use of Laboratory Animals. Significant deficiencies in the institution's program must be identified and the institution must adhere to an approved plan and schedule for correction of the deficiencies.

The policy shall become effective December 31, 1985. Instructions regarding implementation follow the text of the policy.

- (2) Sample Animal Welfare Assurance. The Office for Protection from Research Risks (OPRR), NIH, which is responsible for the general administration and coordination of the PHS Policy has developed a sample assurance to assist PHS awardee institutions in developing an assurance in accordance with the revised policy. Institutions that are presently conducting PHS-supported research in accordance with an approved Animal Welfare Assurance may continue to do so in accordance with the conditions of that assurance. However, these institutions are encouraged to implement the revised policy as soon as it is feasible to do so, and must submit a new assurance to OPRR in accordance with the revised policy by January 1, 1986. Institutions are expected to begin operating under their new assurance as of January 1, 1986.
- (3) U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. At the request of the Office of Science and Technology Policy, the Interagency Research Animal Committee (IRAC) developed these Principles based on the Principles incorporated in the 1979 PHS Extramural Animal Welfare Policy and a similar statement adopted by the Council for International Organizations of Medical Science in 1984. IRAC is comprised of representatives from Federal agencies that conduct, support or regulate the use of animals in testing, research and training. Nine Federal agencies have adopted the U.S. Government Principles, including the Department of Health and Human Services, of which PHS is a component. The revised PHS Policy is intended to implement and supplement these U.S. Government Principles.
- (4) Site Visits to Animal Care Facilities: An Addendum. As part of the NIH evaluation of the adequacy of the Animal Welfare Assurance system, NIH conducted a series of ten site visits in 1983. The results of those site visits were published in the April 5, 1984, Special Edition of the NIH Guide for Grants and Contracts. The report contained in this publication is an addendum to the original report and summarizes the results of a series of five additional site visits to institutions that received less than \$5 million in NIH funds during Fiscal Year 1984. These additional site visits were conducted because this category represents the largest number of institutions that have Animal Welfare Assurances. In light of the revised PHS Policy, NIH was particularly interested in how institutions in this funding category would implement stronger requirements for the care and use of laboratory animals. The addendum concludes that these institutions are capable of meeting the requirements of the revised PHS Policy, and includes recommendations that the NIH assist institutions in implementing the revised PHS Policy.

NOTE: The Institute of Laboratory Animal Resources of the National Research Council, National Academy of Sciences, has completed the revision of the Guide for the Care and Use of Laboratory Animals, (Guide). The PHS Policy requires that institutions use the Guide as a basis for developing and implementing an institutional animal care and use program. Therefore, the full text of the revised Guide is published as a Supplement to this Special Edition and will be mailed to all institutions that currently have an Animal Welfare Assurance.

The revised Guide will be published as a booklet in the coming months. Publication of the text in a Supplement to this Special Edition is an interim measure to ensure that institutions receive the new Guide as soon as possible. Copies of the Supplement containing the Guide may be requested from Dr. John Holman, Division of Research Resources, NIH, Building 31, Room 5B59, Bethesda, Maryland 20205.

PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE
OF LABORATORY ANIMALS BY AWARDEE INSTITUTIONS

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PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE
OF LABORATORY ANIMALS BY AWARDEE INSTITUTIONS

I. Introduction

It is the policy of the Public Health Service (PHS) to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training and biological testing activities (hereinafter referred to as activities) supported by the PHS. The PHS endorses the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training" developed by the Interagency Research Animal Committee (IRAC). This policy is intended to implement and supplement those Principles.

II. Applicability

This policy is applicable to all PHS-supported activities involving animals, whether the activities are performed at an awardee institution or any other institution and conducted in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals shall comply with this policy, or provide evidence to the PHS that acceptable standards for the humane care and use of the animals in PHS-supported activities will be met. No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this policy for PHS-supported activities, or unless the individual makes other arrangements with the PHS. This policy does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act, and other Federal statutes and regulations relating to animals.

III. Definitions

A. Animal

Any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes.

B. Animal Facility

Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

C. Animal Welfare Act

Public Law 89-544, 1966, as amended, (P.L. 91-579 and P.L. 94-279) 7 U.S.C. 2131 et. seq. Implementing regulations are published in the Code of Federal

Regulations (CFR), Title 9, Subchapter A, Parts 1, 2, 3 and 4, and are administered by the U.S. Department of Agriculture.

D. Animal Welfare Assurance or Assurance

The documentation from an awardee or a prospective awardee institution assuring institutional compliance with this policy.

E. Guide

Guide for the Care and Use of Laboratory Animals, DHEW, NIH Pub. No. 78-23, 1978 edition or succeeding revised editions.

F. Institution

Any public or private organization, business, or agency (including components of Federal, state and local governments).

G. Institutional Official

An individual who has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of this policy will be met.

H. Public Health Service

The Public Health Service includes the Alcohol, Drug Abuse, and Mental Health Administration, the Centers for Disease Control, the Food and Drug Administration, the Health Resources and Services Administration, and the National Institutes of Health.

I. Quorum

A majority of the members of the Institutional Animal Care and Use Committee.

IV. Implementation by Awardee Institutions

A. Animal Welfare Assurance

No activity involving animals will be supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with this policy for PHS-supported activities. Assurances shall be submitted to the Office for Protection from Research Risks (OPRR), Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 4B09, Bethesda, Maryland 20205. The Assurance shall be typed on the institution's letterhead and signed by an institutional official. OPRR will provide the applicant institution with necessary instructions and an example of an acceptable Assurance. All Assurances submitted to the PHS in accordance with this policy will be evaluated by OPRR to determine the adequacy of the institution's proposed program for the care and use of animals in PHS-supported activities. On the basis of this evaluation OPRR may approve or disapprove the Assurance, or negotiate an approvable Assurance with the

institution. Approval of an Assurance will be for a specified period of time (no longer than five years) after which time the institution must submit a new Assurance to OPRR. OPRR may limit the period during which any particular approved Assurance shall remain effective or otherwise condition, restrict, or withdraw approval. Without an applicable PHS approved Assurance no PHS-supported activity involving animals at the institution will be permitted to continue.

1. Institutional Program for Animal Care and Use

The Assurance shall fully describe the institution's program for the care and use of animals in PHS-supported activities. The PHS requires institutions to use the Guide for the Care and Use of Laboratory Animals (Guide) as a basis for developing and implementing an institutional program for activities involving animals. The program description must include the following:

- a. a list of every branch and major component of the institution, as well as a list of every branch and major component of any other institution which is to be included under the Assurance;
- b. the lines of authority and responsibility for administering the program and ensuring compliance with this policy;
- c. the qualifications, authority and responsibility of the veterinarian(s) who will participate in the program;
- d. the membership list of the Institutional Animal Care and Use Committee(s)^{1/} (IACUC) established in accordance with the requirements set forth in IV.A.3.;
- e. the procedures which the IACUC will follow to fulfill the requirements set forth in IV.B.;
- f. the health program for personnel who work in laboratory animal facilities or have frequent contact with animals;

^{1/} The name Institutional Animal Care and Use Committee (IACUC) as used in this policy is intended as a generic term for a committee whose function is to ensure that the care and use of animals in PHS-supported activities is appropriate and humane in accordance with this policy. However, each institution may identify the committee by whatever name it chooses. Membership and responsibilities of the IACUC are set forth in IV.A.3. and IV.B.

- g. the gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species, of animals in each facility; and
- h. any other pertinent information requested by OPRR.

2. Institutional Status

Each institution must assure that its program and facilities are in one of the following categories:

Category 1 - Accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or other accrediting body recognized by PHS.^{2/}

Category 2 - Evaluated by the Institution. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once each year. The IACUC shall use the Guide for the Care and Use of Laboratory Animals as a basis for evaluating the institution's program and facilities. A report of the IACUC evaluation shall be submitted to the institutional official and updated on an annual basis.^{3/} The initial report shall be submitted to OPRR with the Assurance. Annual reports of the IACUC evaluation shall be maintained by the institution and made available to OPRR upon request. The report must contain a description of the nature and extent of the institution's adherence to the Guide and this policy.^{4/} The report must identify specifically any departures from provisions of the Guide and this policy, and state the reasons for each departure. If

^{2/} As of the issuance date of this policy the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC).

^{3/} The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to conduct or assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

^{4/} If some of the institution's facilities are accredited by AAALAC or other accrediting body recognized by PHS, the report should identify those facilities and need not contain any further information about evaluation of those facilities.

program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule for correcting each deficiency. The report must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, in the judgment of the IACUC and the institutional official, is or may be a threat to the health or safety of the animals. Failure of the IACUC to conduct an annual evaluation and submit the required report to the institutional official may result in PHS withdrawal of its approval of the Assurance.

3. Institutional Animal Care and Use Committee

- a. Each institution shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to oversee the institution's animal program, facilities and procedures.
- b. The Assurance must include the names, position titles and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall include at least:
 - (1) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the institution;
 - (2) one practicing scientist experienced in research involving animals;
 - (3) one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and
 - (4) one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.
- c. An individual who meets the requirements of more than one of the categories detailed in IV.A.3.b.(1)-(4) may fulfill more than one requirement. However, no committee may consist of less than five members.

B. Functions of the Institutional Animal Care and Use Committee

As an agent of the institution the IACUC shall, with respect to PHS-supported activities:

1. review at least annually the institution's program for humane care and use of animals;
2. inspect at least annually all of the institution's animal facilities, including satellite facilities;

3. review concerns involving the care and use of animals at the institution;
4. make recommendations to the institutional official regarding any aspect of the institution's animal program, facilities or personnel training;
5. review and approve, require modifications in (to secure approval) or withhold approval of those sections of PHS applications or proposals related to the care and use of animals as specified in IV.C.;
6. review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and
7. be authorized to suspend an activity involving animals in accord with specifications set forth in IV.C.6.

C. Review of PHS Applications and Proposals

1. In order to approve applications and proposals or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those sections related to the care and use of animals and determine that the proposed activities are in accord with this policy. In making this determination, the IACUC shall confirm that the activity will be conducted in accord with the Animal Welfare Act insofar as it applies to the activity, and that the activity is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the activity conforms with the institution's Assurance and meets the following requirements:
 - a. Procedures with animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design.
 - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly sacrificed at the end of the procedure or, if appropriate, during the procedure.
 - d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling and use of the species being maintained or studied.
 - e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - g. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia,^{5/} unless a deviation is justified for scientific reasons in writing by the investigator.
- 2. Prior to the review, each IACUC member shall be provided with a list of applications and proposals to be reviewed. Those sections of applications and proposals that relate to the care and use of animals shall be available to all IACUC members, and any member of the IACUC may upon request obtain full committee review of those sections. If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those sections and have the authority to approve, require modifications in (to secure approval) or request full committee review of those sections. If full committee review is requested, approval of those sections may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an application or proposal in which the member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
 - 3. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an application or proposal or vote with the IACUC.
 - 4. The IACUC shall notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an application or proposal, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
 - 5. The IACUC shall conduct continuing review of applications and proposals covered by this policy at appropriate intervals as determined by the IACUC, but not less than once every three years.

^{5/} Journal of the American Veterinary Medical Association (JAVMA), 1978, Vol. 173, No. 1, pp. 59-72, or succeeding revised editions.

6. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.l.a.-g. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
7. If the IACUC suspends an activity involving animals, the institutional official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action and report that action with a full explanation to OPRR.
8. Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve those sections of an application or proposal related to the care and use of animals if they have not been approved by the IACUC.

D. Information Required in Applications and Proposals Submitted to PHS

1. All Institutions

Applications and proposals submitted to PHS that involve the care and use of animals shall contain the following information:

- a. identification of the species and approximate number of animals to be used;
- b. rationale for involving animals, and for the appropriateness of the species and numbers to be used;
- c. a complete description of the proposed use of the animals;
- d. assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- e. a description of any euthanasia method to be used.

2. Institutions That Have an Approved Assurance

Applications or proposals covered by this policy from institutions which have an approved Assurance on file with OPRR shall include verification of approval by the IACUC of those sections related to the

care and use of animals. With the authorization of PHS, such verification may be filed at a time not to exceed 60 days after submission of applications or proposals.^{6/}

If verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification shall state the modifications, if any, required by the IACUC. The verification shall be signed by an individual authorized by the institution, but need not be signed by the institutional official who signed the Assurance.

3. Institutions That Do Not Have an Approved Assurance

Applications and proposals involving animals from institutions that do not have an approved Assurance on file with OPRR shall contain a declaration that the institution will establish an IACUC and submit an Assurance upon request by OPRR. After OPRR has requested the Assurance, the institution shall establish an IACUC as required by IV.A.3. and the IACUC shall review those sections of the application or proposal as required by IV.C. The institution shall then submit to OPRR the Assurance and verification of IACUC approval. The verification shall state the modifications, if any, required by the IACUC. The verification shall be signed by an individual authorized by the institution, but need not be signed by the institutional official who signed the Assurance.

E. Recordkeeping

1. The awardee institution shall maintain:

- a. an Assurance approved by the PHS;
- b. minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;
- c. records of applications, proposals and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
- d. records of any IACUC reports and recommendations as forwarded to the institutional official; and
- e. records of accrediting body determinations.

2. All records shall be maintained for at least three years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall

^{6/} Until further notice, PHS hereby authorizes all institutions with approved Assurances to file verification of IACUC approval either along with the application or proposal or within 60 days of submission of the application or proposal. From time to time PHS will reevaluate this blanket authorization. Any decision to withdraw this authorization will take place only after ample opportunity is provided for comment by the public.

be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

F. Reporting Requirements

1. On or before each anniversary of approval of its Assurance, the institution shall report in writing to OPRR:
 - a. any change in the institution's program or facilities which would place the institution in a different category than specified in its Assurance (see IV.A.2.);
 - b. any change in the description of the institution's program for animal care and use as required by IV.A.1.a.-h.;
 - c. any changes in IACUC membership; and
 - d. if the institution's program and facilities are in Category 2 (see IV.A.2.), verification that the IACUC has conducted an annual evaluation of the institution's program and facilities and submitted the evaluation to the institutional official.
2. Institutions that have no changes to report as specified in IV.F.1. a.-c. shall submit a letter to OPRR stating that there are no changes.
3. Institutions shall provide OPRR promptly with a full explanation of the circumstances and actions taken with respect to:
 - a. any serious or continuing noncompliance with this policy;
 - b. any serious deviation from the provisions of the Guide; or
 - c. any suspension of an activity by the IACUC.

V. Implementation by PHS

A. Responsibilities of OPRR.

OPRR is responsible for the general administration and coordination of this policy and will:

1. request and negotiate, approve or disapprove, and, as necessary, withdraw approval of Assurances;
2. distribute to executive secretaries of initial review and technical evaluation groups, and to PHS awarding units, lists of institutions that have an approved Assurance;
3. advise awarding units and awardee institutions concerning the implementation of this policy;

4. evaluate allegations of noncompliance with this policy;
5. have the authority to review and approve or disapprove waivers to this policy (see V.D.); and
6. conduct site visits to selected institutions.

B. Responsibilities of PHS Awarding Units

PHS awarding units may not make an award for an activity involving animals unless the institution submitting the application or proposal is on the list of institutions that have an approved Assurance on file with OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals in PHS-supported activities. If an institution is not listed, the awarding unit will ask OPRR to negotiate an Assurance with the institution before an award is made. No award shall be made until the Assurance has been submitted by the institution, approved by OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals in PHS-supported activities.

C. Conduct of Special Reviews/Site Visits

Each awardee institution is subject to review at anytime by PHS staff and advisors, which may include a site visit, in order to assess the adequacy of the institution's compliance with this policy.

D. Waiver

Institutions may request a waiver of a provision or provisions of this policy by submitting a request to OPRR. No waiver will be granted unless sufficient justification is provided and the waiver is approved in writing by OPRR.

INSTRUCTIONS FOR IMPLEMENTATION OF THE REVISED PHS POLICY

The revised PHS Policy for the Humane Care and Use of Laboratory Animals will become effective December 31, 1985. Institutions which currently have an approved Animal Welfare Assurance on file with the Office for Protection from Research Risks (OPRR) must submit to OPRR by January 1, 1986, a revised Assurance developed in accordance with the new policy. These institutions are encouraged to begin implementing the revised policy as soon as possible and are expected to begin operating under their new Assurance as of January 1, 1986.

Applications and proposals submitted to the PHS after January 1, 1986, must meet the requirements of the revised PHS Policy. Section IV.D.1. of the revised policy requires all applications and proposals to contain specific information regarding the proposed use of laboratory animals. Applications and proposals received after January 1, 1986, that do not contain the information required in Section IV.D.1. will be considered incomplete and may be deferred for a later review. (The information required by Section IV.D.1. of the revised policy should appear in the appropriate section of each grant application form, for example, Section 2.F. of the PHS Grant Application Form 398.)

Institutions That Have an Approved Assurance

Applications and proposals submitted to the PHS after January 1, 1986, must contain verification that the institutional animal care and use committee (IACUC) has approved those sections of the application or proposal related to the care and use of laboratory animals. PHS prefers that verification of IACUC approval be submitted along with the application or proposal, however, it may be submitted within 60 days of submission of the application or proposal. If verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification must state any modifications required by the IACUC.

In the near future, PHS will institute a standardized method for institutional submission of IACUC approval. In the interim, verification of IACUC approval must be submitted via a letter from the institution to PHS. The letter must be signed either by the institutional official who signed the institution's Animal Welfare Assurance, or by another individual authorized by the institution to provide verification of IACUC approval.

The following example may be used in preparing such letters of verification.

EXAMPLE OF ACCEPTABLE VERIFICATION

Date

Division of Research Grants*
National Institutes of Health
5333 Westbard Avenue
Westwood Bldg., Room 240
Bethesda, MD 20205

Dear Sir:

The following application submitted to the Public Health Service was
reviewed and approved by this institution's Animal Care and Use Committee
on (insert date of approval) :

Title of application:
Name of Principal Investigator:
Name of Institution:

This institution has an Animal Welfare Assurance on file with the Office for Protection
from Research Risks. The Assurance number is _____. (Insert old assurance number
until a new assurance number is assigned.)

As a condition of approval, this institution's Animal Care and Use Committee required
the following modifications to the above referenced application:**

(Signature)
(Title)

* This address should be used for submission with grant applications. If verification is
submitted subsequent to the submission of the application, it should be addressed to
the Executive Secretary of the initial review group designated on the card returned to
the institution acknowledging receipt of the application. For contract proposals,
verification should be addressed to the contract officer.

** This information is required when the modifications are not reflected in the original
grant application or contract proposal.

Institutions That Do Not Have an Approved Assurance

Institutions that do not have an approved Animal Welfare Assurance on file with OPRR must submit, with the application or proposal, a declaration that the institution will establish an Institutional Animal Care and Use Committee and submit an Assurance upon request by OPRR. The following letter is an example of an acceptable declaration:

EXAMPLE OF ACCEPTABLE DECLARATION

Date

Division of Research Grants*
National Institutes of Health
5333 Westbard Avenue
Westwood Bldg., Room 240
Bethesda, MD 20205

Dear Sir:

This institution does not have an Animal Welfare Assurance on file with the Office for Protection from Research Risks (OPRR) to cover the following application:

Title of application:
Name of Principal Investigator:
Name of Institution:

This institution will establish an Institutional Animal Care and Use Committee, have the application reviewed by the IACUC and submit an Animal Welfare Assurance, upon request, to OPRR.

(Signed by institutional official)
(Title)

* For contract proposals, this letter should be addressed to the contract officer.

If an award is likely to be made, OPRR will then request that the institution submit an Assurance. The institution's Animal Care and Use Committee (IACUC) must review those sections of the application or proposal related to the care and use of animals and submit the Assurance and verification of IACUC approval to OPRR. The Example of an Acceptable Verification Letter (see previous section on Institutions That Have an Approved Assurance) may be followed in submitting verification of IACUC approval.

Sample Animal Welfare Assurance

Attached is a sample Animal Welfare Assurance prepared by the Office for Protection from Research Risks to assist awardee institutions in developing an assurance in accord with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (revised June 1985). This sample includes all of the necessary elements for compliance with the PHS Policy. There are several areas in an assurance which require that the institution provide specific information regarding procedures, policies and responsibilities and qualifications of personnel of the institution. The Animal Welfare Assurance will need to be tailored to meet the administrative and research requirements for each institution. This sample assurance document provides suggestions and examples of the kind of information that is to be provided by the institution in accordance with the PHS Policy. The sample refers to an Institutional Animal Care and Use Committee (IACUC), a generic name for the institutional committee established in accord with the PHS Policy to fulfill the functions outlined in the policy. In preparing its assurance document, each institution should consistently use whatever name it has assigned to that committee. More than one IACUC may be established to meet the needs of an institution. The assurance must identify each IACUC established by the institution.

This sample is intended as an aid to your institution in developing an Animal Welfare Assurance. Close adherence to the format will facilitate the review process. Questions should be directed to the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20205, (301) 496-7005.

INSTITUTIONAL LETTERHEAD

(Name of Institution)

Assurance of Compliance with PHS Policy on Humane
Care and Use of Laboratory Animals by Awardee Institutions

(Name of Institution), hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, hereinafter referred to as PHS Policy.

I. Applicability

This assurance is applicable to all research, research training, and biological testing activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-supported activity by this institution. "Institution" includes the following branches and major components of **(name of institution) (list every branch and major component covered by this assurance)**. (If applicable), "Institution" also includes the following branches and major components of **(name(s) of other institution(s) to be included under this assurance) (list every branch and major component of other institution(s) to be covered by this assurance)**.

II. Institutional Policy

- A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This institution is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.
- C. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this assurance. As partial fulfillment of this responsibility this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this assurance as well as all other applicable laws and regulations pertaining to animal care and use.
- D. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with this policy are:

(Describe or diagram the organization of the administration and staff, including the Institutional Animal Care and Use Committee, the institutional official and the veterinarian.)

- B. The qualifications, authority and responsibility of the veterinarian(s) who will participate in the program include:

(Indicate professional or academic degrees and the number of years of pertinent training or experience in laboratory animal medicine. Describe the veterinarians functions and responsibilities insofar as they relate to implementing recommendations in the Guide for the Care and Use of Laboratory Animals.)

- C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the compositional requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the names, position titles and earned degrees or other credentials of the IACUC chairperson and members.

- D. The IACUC will:

1. Review at least annually the institution's program for humane care and use of animals.
2. Inspect at least annually all of the institution's animal facilities, including satellite facilities.
3. Review concerns involving the care and use of animals at the institution.
4. Make written recommendations to **(insert name or title of institutional official signing assurance)** regarding any aspect of the institution's animal program, facilities, or personnel training.
5. Review and approve, require modifications in (to secure approval) or withhold approval of those sections of applications or proposals to PHS related to the care and use of animals as set forth in the PHS Policy at IV.C.
6. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C.
7. Notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4.
8. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6.

- E. The procedures which the IACUC will follow to fulfill the requirements set forth in the PHS Policy at IV.B. are:

(Describe how the IACUC will fulfill each of the functions set forth in the PHS Policy at IV.B. Include how often the IACUC will meet, how often it will inspect facilities, and how the inspections will take place. Describe the procedures the IACUC will follow to address any concerns, and how recommendations will be developed and forwarded to the institutional official. The channels for receiving applications and proposals, and for reporting the results of IACUC review of applications and proposals should be addressed.)

F. The individual(s) authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is (insert name of individual).

G. The health program for personnel who work in laboratory animal facilities or have frequent contact with animals is:

(Describe the institution's occupational health program, including the frequency of tuberculosis tests, if any, requirements for medical examinations, etc. The institution may submit a memorandum or pamphlet (if one exists) which informs animal care and use staff of institutional policies regarding health screening or tests.)

H. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory, by species, of animals in each facility is: **(This information may be provided in an attached chart.)**

IV. Institutional Status

As specified in the PHS Policy at IV.A.2. as Category 1, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by the American Association for Accreditation of Laboratory Animal Care.

- OR -

As specified in the PHS Policy at IV.A.2 as Category 2, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once each year. The IACUC has and will continue to use the Guide as a basis for evaluating the institution's programs and facilities. The report of the IACUC evaluation has been submitted to **(insert name or title of institutional official signing assurance)** and a copy of the report is attached. The report contains a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide are identified specifically and reasons for each departure are stated. Where program or facility deficiencies are noted, the report contains a reasonable and specific plan and schedule for correcting each deficiency. The report distinguishes significant deficiencies from minor deficiencies. Annual reports of the IACUC evaluation will be maintained by this institution and made available to OPRR upon request.

V. Recordkeeping

- A. This institution will maintain for at least three years:
 - 1. A copy of this assurance as approved by PHS.
 - 2. Minutes of IACUC meetings, including records of attendance, activities of the committee and committee deliberations.
 - 3. Records of applications, proposals and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
 - 4. Records of any IACUC reports and recommendations as forwarded to **(insert name or title of institutional official signing assurance)**.
 - 5. Records of accrediting body determinations.
- B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. On or before each anniversary of approval of this assurance, this institution will report in writing to the Office for Protection from Research Risks (OPRR):
 - 1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this assurance, or any changes in IACUC membership. If there are no changes to report, this institution will submit a letter to OPRR stating that there are no changes.
 - 2. **(To be included only in assurance submitted by institutions whose program and facilities are not fully accredited by the American Association for the Accreditation of Laboratory Animal Care).** Verification that the IACUC has conducted an annual evaluation of the institution's program and facilities and submitted the evaluation to **(insert name or title of institutional official signing assurance)**.
- B. This institution will provide the OPRR promptly with a full explanation of the circumstances and actions taken with respect to:
 - 1. Any serious or continuing noncompliance with the PHS Policy.
 - 2. Any serious deviations from the provisions of the Guide.
 - 3. Any suspension of an activity by the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: _____

Title: _____

Address: _____

Phone: _____

Signature: _____ Date: _____

B. PHS Approving Official

Name: _____

Title: _____

Address: _____

Phone: _____

Signature: _____ Date: _____

C. Effective date of assurance: _____

D. Expiration date of assurance: _____

INSTITUTION NAME _____

MEMBERSHIP OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

ASSURANCE NUMBER _____

DATE _____

Member Name	Degrees or Other	Position	Affiliation with	Address and Phone
First MI Last	Credentials	Title (if any)	Institution (if none, state)	Number of Chairperson

*

**

* Indicates Chairperson
** Indicates Non-scientific Member

ANIMAL CARE AND USE FACILITIES

ASSURANCE NUMBER

DATE _____

[illegible]

*(Institutions may identify animal areas in any manner they choose, e.g., by using initials or an I.D. number. However, the exact title and location of an area must be available to OPRR upon request.)

U.S. Interagency Research Animal Committee

PRINCIPLES FOR THE UTILIZATION AND CARE OF VERTEBRATE
ANIMALS USED IN TESTING, RESEARCH AND TRAINING

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible institutional official shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.¹
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or

¹ For guidance throughout these Principles the reader is referred to the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal research committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

SITE VISITS TO ANIMAL CARE FACILITIES: AN ADDENDUM

I. INTRODUCTION AND BACKGROUND

Following publication of the Report: SITE VISITS TO ANIMAL CARE FACILITIES, A Report to the Director of the National Institutes of Health, March 1984, the National Institutes of Health (NIH) conducted a further assessment of its Animal Welfare Assurance System. Only institutions receiving total support of less than \$5 million in funds from the NIH in Fiscal Year 1984 (FY '84) were visited in the second series because this category had the largest number of institutions filing Assurance Statements with the NIH Office for the Protection from Research Risks (OPRR) and was least well sampled in the first series. Additionally, in light of proposed changes in the Public Health Service (PHS) Animal Welfare Policy emphasizing more explicit procedures and more active animal care committees, the NIH was particularly interested in observing how institutions with a relatively modest-sized program of biomedical research approach their commitments to ensure the appropriate care and use of laboratory animals. This report, prepared as an addendum to the original report, summarizes the results of a series of site visits to five (5) institutions.

II. METHODS

To carry out the proposed site visits, a stratified, random sample of five institutions that do not have accreditation from the American Association for Accreditation of Laboratory Animal Care (AAALAC) but operate under approved assurances indicating full compliance with PHS policy were selected. One institution receiving less than \$5 million in FY '84 was chosen from each of the ten geographic regions of the Department of Health and Human Services. The ten institutions were randomly ordered and the following institutions in each of the first five regions were selected for site visits:

<u>DHHS REGION</u>	<u>INSTITUTION/LOCATION</u>
5	OAKLAND UNIVERSITY, ROCHESTER, MI.
3	NORFOLK STATE UNIVERSITY, NORFOLK, VA.
10	OREGON STATE UNIVERSITY, CORVALLIS, OR.
7	RHODE ISLAND HOSPITAL, PROVIDENCE, RI.
8	RICE UNIVERSITY, HOUSTON, TX.

The protocol for these visits was the same as the one used for the first ten visits. It was designed to evaluate an institution's mechanisms for complying with its Statement of Assurance at every level of participation: administrative organization and commitment; responsibilities and activities of the animal care committee; investigators' understanding and practice of animal care procedures; veterinary oversight; and condition and design of animal facilities. In all instances, the site visits were performed in one day during the months of July and August 1984 and followed an agenda similar to the one used for the first ten visits. The site visit teams were composed of four members. To maintain continuity, all of the

visits were chaired by Dr. Louis R. Sibal of the NIH Office of Extramural Research and Training and included a scientist or administrator from the OPRR and two non-federal consultants--a veterinarian experienced in laboratory animal medicine and a biomedical scientist currently conducting research requiring laboratory animals.

Finally, the descriptions of the oversight procedures are deliberately brief in this report to avoid unnecessary overlap and duplication with the Report issued in March 1984. All findings, conclusions and recommendations are reported in general terms so that they may be applied to the diverse scientific institutions supported by the NIH.

III. FINDINGS

In general, institutional administrators, scientists and animal care personnel with whom the site visitors spoke were supportive of NIH's assessment efforts. They cooperated by providing relevant documents such as United States Department of Agriculture inspection reports and animal care committee minutes prior to and during the visits and responded candidly to questions about the PHS policy and the NIH assurance process in relation to their animal care programs or research interests. This section is divided into five parts and summarized as follows:

A. Administrative Support

Objective: To evaluate the nature and extent of support provided by administrative officials to institutional laboratory animal programs.

Senior administrative officials at each of the five institutions were knowledgeable of the animal programs for which they were responsible. Their interest in animal welfare issues seemed heightened by the recent emphasis on animal welfare legislation, antivivisectionist activities and the previous site visits undertaken by the NIH. They described institutional oversight systems with relatively simple organizational structures. Most officials relied heavily upon the leadership and dedication of one or two individuals, usually the animal care committee chairman, the veterinarian or a senior scientist, and upon informal contacts with other scientists and technicians working with laboratory animals.

Two of the institutions were planning to expand their biomedical research programs by adding faculty and/or by making significant capital investments in new facilities and equipment. In these cases, the administrators were strongly supportive of developing more extensive animal care programs and had taken steps to formalize oversight procedures, distributing the responsibility for protocol review and facilities management to other officials or to the animal care committee. The proposed PHS policy, which would vest more responsibility in the local animal care committee, appears to have been an important impetus for such actions. One institution had established a strong central authority for managing its animal care programs. The others maintained loosely structured but functional systems.

B. Animal Care Committees

Objective: To assess the quality of oversight of the institution's animal care program.

In general, the site visitors found that animal care committees met most of present policy requirements. The committees were composed of appropriate representatives of the user community, usually one or more practicing scientists, a veterinarian and an institutional official. In those institutions where the biomedical research program was small in size and scope the veterinarian, usually hired on a consulting basis, was neither specially trained in laboratory animal medicine nor fully responsible for housing, feeding and care of the animals. All but one of the committees met at least annually to inspect animal research facilities and review the institutions' programs for animal care and use. The proposed PHS policy requirement that animal care committees include a lay member had already been addressed by three of the committees. Because these nonscientists by definition were not part of the user community, committee activity was usually more formalized to accommodate their participation. Committees which had not yet appointed lay members were not opposed to doing so.

The committee members were concerned and knowledgeable individuals, but their responsibilities were not well defined. Each committee acted in an advisory capacity to the institutional official and represented the needs and concerns of laboratory animal users at that institution. However, the concerns were often budgetary, dealing with such problems as the increased costs of doing research, purchasing new equipment and making capital improvements. Allocating space, providing guidelines for operating animal facilities and setting per diem charges for animal maintenance were usually the responsibility of the chairperson, the veterinarian or the administrator.

Proposed changes in the PHS policy caused some of the institutions to redefine the duties of their animal care committees. Three of the committees had already developed standard procedures for the review of all applications and proposals involving animals submitted to the NIH by the institutional investigators. Even though most institutional officials seemed willing to upgrade committee activities to include the review of experimental protocols involving animals, they felt that this task was primarily the responsibility of NIH study sections.

C. INVESTIGATORS

Objective: To determine the degree of interaction between investigators and officials and/or personnel associated with the animal care program.

Most investigators interviewed at each institution were generally familiar with both the NIH assurance system and their institution's policies and procedures for laboratory animal research. Because of the relatively small scale of these programs, these investigators often assumed the responsibility for ordering animals, purchasing supplies and equipment, maintaining the animals and the training of technicians and caretakers usually recruited from the student body. They were familiar with the activities of the animal care committee; in fact, in some smaller institutions the same investigators were members of the animal care committee.

Few investigators had complaints about the quality of care provided for their animals. However, upon further questioning, some investigators said that they had not been provided sufficient advice from a veterinarian in the planning and

execution of their experiments. Some expressed the desire for facilities with more sophisticated animal holding areas to avoid problems associated with poor environmental control and naturally-occurring diseases--factors that might affect the quality of their experimental results.

D. VETERINARY CARE.

Objective: To assess the availability and degree of involvement of qualified veterinarians in institutional animal care programs.

For the current series of visits, only one of the five veterinarians interviewed played a major role in the institution's animal care program (e.g. hiring and training personnel, selecting animal suppliers, advising on experimental procedures including the administration of anesthetics and analgesics, maintaining the animal care facility). The remaining institutions acquired the services of consulting veterinarians often on a part-time basis; their responsibilities were generally limited to such activities as participating in the animal care committee meetings, inspecting animal facilities, and handling special problems or animal medical emergencies as necessary. Four institutions employed veterinarians who had pertinent experience in laboratory animal medicine; however, only two veterinarians were qualified by formal training. One institution had not formally secured the services of a veterinarian.

In general, the small number of investigators using animals, the use of noninvasive experimental procedures and the acute nature of most of the projects did not require a great deal of veterinary guidance. The lack of ready access to a well-trained veterinarian did not seem to jeopardize the general health and well-being of the experimental animals. However, the site visitors noted that marginal or limited veterinary expertise placed severe constraints on the nature and scope of the projects that could be carried out satisfactorily.

E. ANIMAL FACILITIES

Objective: To inspect the physical plant and determine the quality of animal care provided by the institution.

Because the space designated for animal care was not extensive, the site visitors inspected every area where animals were maintained and treated at the five institutions visited. Four had centralized laboratories, one had three additional satellite laboratories; the other institution maintained three separate laboratories. In general, the animals were well-housed in facilities having good sanitation. Light, environmental and security controls were simple but adequate. The teams found little or no evidence of overcrowding or sickness; some facilities were underused, having relatively few animal users.

Three of the facilities had been renovated within the past two years. They were designed appropriately with reasonable space allocations for animals and moderate degrees of containment; however, specialized laboratories for such activities as surgery or experimental manipulation of animals were not common. Based on the nature of the research activities at most of the institutions--short term, acute studies--the animal facilities were adequate for the limited numbers and species of animals used. In two instances, the site visitors examined the renovation plans that had been under consideration for several years. In one case, however, it was evident that renovations were very

recent; animal care rooms had just been freshly cleaned and painted, suggesting that the special attention given to the premises was intended to impress the site visitors. Even with improvements, existing deficiencies made this institution's current program only marginally acceptable.

III. CONCLUSIONS AND RECOMMENDATIONS

A. CONCLUSIONS

The programs for the care and use of laboratory animals at the five institutional sites selected for this study met or exceeded the minimum standards set forth in the current PHS policy. Although the sample size is still very small--nine institutions in this funding category were visited in two years--the findings reported herein help to answer questions relevant to institutions that are less oriented to the conduct of biomedical research but still receive support--in some cases substantial--from the NIH. We conclude:

1. Institutions receiving less than \$5 million per year in NIH research funds are capable of meeting the responsibilities imposed by the PHS policy. Therefore, reliance on voluntary compliance remains a realistic approach to promoting the proper care and use of laboratory animals in biomedical research.
2. Institutions within this same group are capable of assuming additional responsibilities in response to proposed changes in the PHS policy.

These conclusions are based on the following findings:

- o No incidents of animal abuse were observed.
- o Most institutional officials provided adequate leadership and responded to the needs of institutional animal care programs. Communication problems were few because of the opportunities for frequent contacts among the institutional administrators, investigators and animal care personnel.
- o Some institutional animal care committees were recently reorganized for the purpose of assuming additional responsibilities required by the proposed PHS policy; three institutions' rosters included lay members. Institutional committees were potentially capable of reviewing protocols with respect to the adequacy of the care and use of laboratory animals in research projects. Compared to those institutions in higher funding categories, fewer complaints were registered about the burden of these reviews. However, despite these capabilities, the site visitors found that most of the committees needed to improve their advisory or oversight roles.
- o With some exceptions, the lack of adequate veterinary oversight in some of the institutions forced investigators to become self-reliant; however, when available, most consulting veterinarians provided helpful guidance.
- o The areas designated as animal care facilities were adequate to excellent. However, most would not have been appropriate for long-term maintenance or specialized treatment of animals.

B. RECOMMENDATIONS

1. The NIH should continue assessing the adequacy of its traditional assurance system by visiting additional awardee institutions. When formulating further site visits plans, the institutions should be selected randomly using different stratification criteria than the first two series to ensure more nearly uniform sampling of the universe of settings in which NIH-funded animal experimentation is conducted.
2. The NIH should consider a plan for helping institutions obtain appropriate veterinary care and advice.
3. The NIH should undertake a program for helping institutions understand fully their responsibilities in implementing a successful program of laboratory animal care.

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NIH Guide for Grants and Contracts

Vol. 14, No. 9, July 18, 1985

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AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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REVISION OF ANNOUNCEMENT

GERIATRIC LEADERSHIP ACADEMIC AWARD (K07)

P.T. 34; K.W. 0710010

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA) has revised the dates for receipt of applications for the Geriatric Leadership Academic Award which were published in the NIH Guide for Grants and Contracts, Vol. 13, No. 10, September 7, 1984. Applications will be reviewed three times a year according to the following schedule:

<u>Applications Received By:</u>	<u>Council Review</u>	<u>Earliest Start Date</u>
October 1	May	June 1*
February 1	September	October 1
June 1	February	March 1*

*of the year following receipt

NOTICECANCER CENTERS PROGRAM

P.T. 04; K.W. 0715035, 0710030

NATIONAL CANCER INSTITUTE

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) announces the availability of revised guidelines for the existing Cancer Center Support Grant program as well as guidelines for the newly created Consortium Cancer Center Support Grant program. The latter program is designed to support a consortium of the various cancer resources of a region in the conduct of cancer control and related research. The guidelines for both programs are included in a single document, "Guidelines 1985: Cancer Center Support Grant and Consortium Cancer Center Support Grant." Applicants are requested to submit a letter of intent four to six months in advance of the regular due date for applications (October 1, February 1, June 1).

Interested investigators should obtain copies of "Guidelines 1985" from:

Chief, Cancer Centers Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 714
8300 Colesville Road
Silver Spring, Maryland 20205-4200

Telephone: 301 - 427-8663

NOTICE

CANCER EDUCATION GRANTS (R25)

P.T. 25; K.W. 0785140, 0715035

NATIONAL CANCER INSTITUTE

Applications are received February 1, June 1, and October 1. An applicant may request support for (1) oncologic curriculum development, (2) medical and dental student summer cancer research experiences; (3) short-term cancer research education for prebaccalaureate minority students from nearby colleges having a student body predominantly minority in constitution; or (4) continuing cancer education. An application may embody only one of the above elements, or any combination of them.

Additional information may be obtained from:

Program Director
Cancer Training Branch, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 424
Bethesda, Maryland 20205-4200

Telephone: (301) 427-8898

NOTICESMALL GRANTS AND SPECIAL EMPHASIS RESEARCH CAREER AWARD (SERCA) GRANTS

P.T. 34; K.W. 0710030, 0725020

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Effective immediately, the application receipt dates for Small Grants (R03) and SERCA Grants (K01) supported by the National Institute for Occupational Safety and Health (NIOSH) are changed to November 1, March 1, and July 1. In addition, an expedited secondary review will be made for R03 and K01 grants so that research can be initiated sooner on awarded grants. All other programmatic aspects remain unchanged as described below. Additional information may be obtained from:

Roy M. Fleming, Sc.D.
Associate Director for Grants
National Institute for Occupational
Safety and Hazard
Centers for Disease Control
Building 1 - Room 3053
Atlanta, Georgia 30333

Telephone: 404 - 329-3343

PROGRAM REQUIREMENTS

Small Grants

A small grant application is intended to provide financial support to carry out exploratory or pilot studies, to develop or test new techniques or methods, or to analyze data previously collected. This small grant program is intended for predoctoral graduate students, post-doctoral researchers (within three years following completion of doctoral degree or completion of residency or public health training) and junior faculty members (no higher than assistant professor). If university policy requires that a more senior person be listed as principal investigator, the application should specify that the funds are for the use of a particular student or junior-level person and should include appropriate justification for this arrangement. Though biographical sketches are required only for the person actually doing the work, the application should indicate who would be supervising the research. Small grant applications should be identified as such on the application form.

The total small grant award may comprise direct costs of up to \$15,000 per year and additional indirect costs, as appropriate. The grants may be awarded for up to two years and are thereafter continuable by competitive renewal as a regular research grant. Salary of the principal investigator as well as that of the junior

investigator, if university policy requires a senior person to be listed as the principal investigator, will not be allowed on a small grant, though salaries can be requested for necessary support staff such as laboratory technicians, interviewers, etc.

Special Emphasis Research Career Award (SERCA) Grants

The SERCA is designed to enhance the research capability of individuals in the formative stages of their careers who have demonstrated outstanding potential for contributing as independent investigators to health-related research. Candidates must have had two or more years of relevant postdoctoral experience prior to the submission date. The application must document accomplishments in this period that demonstrate research potential; it must also present a plan for additional experience in a productive scientific environment at domestic institutions that will foster development of a career of independent research in the area of occupational safety and health. The SERCA is not intended for untried investigators, or for productive, independent investigators with significant numbers of publications of high quality, or for persons of senior academic rank (above associate professor or tenured). Moreover, the award is not intended to substitute one source of salary support for another for an individual who is already conducting full-time research, nor is it intended to be a mechanism for providing institutional support. The application must demonstrate that the award will make a difference in and enhance the candidate's development as an independent investigator.

Candidates must indicate a commitment of at least 60 percent time (not necessarily 60% salary) devoted to research under the SERCA grant, although full-time is desirable. Other work in the area of occupational safety and health will enhance the candidate's qualifications but is not a substitute for this requirement. While working closely with one or more advisors, the awardee is expected to develop capabilities in fundamental, applied, and/or clinical research in one of the areas in section IV. At the end of the award period, evidence of independent investigative capability should be present such that the individual is better able to compete in traditional NIOSH research grant activities.

The total grant award may comprise direct costs of up to \$30,000 per year and up to eight percent additional indirect costs. Direct costs may include salary plus fringe benefits, technical assistance, equipment, supplies, consultant costs, domestic travel, publication, and other costs. If the awardee already holds a small grant on the same research topic, the amount of the SERCA may be reduced up to the amount of the small grant. Awards may be up to three years and will not be renewable.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-29-B

REGULATION OF THE CLONED HUMAN BETA-GLOBIN GENE

P.T. 34; K.W. 0745065, 0755035, 0790010, 0755040, 0780020

DIVISION OF BLOOD DISEASES AND RESOURCES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: November 15, 1985

The Blood Diseases Branch of the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA, 85-HL-29-B, may be obtained from staff of the NHLBI.

The program will encourage research addressing approaches to the insertion and regulation of the cloned human beta-globin gene into hematopoietic tissue in culture or in live animals. The use of appropriate vectors and subsequent bone marrow transplantation should allow transfer of new genetic material into intact adult animals. This work should thus provide novel systems in which in vitro manipulated sequences, both regulatory and transcribed, may be studied in normal hematopoietic tissues in culture and in live animals. It is expected that this research will have the potential for advancing our ability to perform gene therapy for beta-thalassemia in the future. However, gene therapy in humans is not the subject of this solicitation.

Requests for copies of the RFA should be addressed to:

Alan S. Levine, Ph.D.
Deputy Chief, Blood Diseases Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 5A12
Bethesda, Maryland 20205

Telephone (301) 496-5911

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-AG-01

NEUROLOGIC, MUSCULAR, PERCEPTUAL AND CARDIOVASCULAR ASPECTS OF
FALLS AND GAIT DISORDERS IN ELDERLY PEOPLE

P.T. 34; K.W. 0715140, 0715005, 0710010, 1002034

NATIONAL INSTITUTE ON AGING

Application Receipt Date: November 15, 1985

I. BACKGROUND INFORMATION

Falls and gait disorders cause pain, fear, suffering, restriction of daily activities, institutionalization and death among older people. The vast majority of the approximately 200,000 hip fractures occurring each year are suffered by elderly people. Many are the result of a fall. The one year mortality of hip fracture victims probably exceeds 20%. Many elderly persons have impairments of gait speed and the inability to climb stairs which restricts their activities.

Falling and gait disorders are not an inevitable accompaniment of old age. They are the result of diseases and conditions and the interactions of diseases and conditions. Some of the diseases and conditions implicated include psychological and cognitive disorders, architectural barriers and distractions, prescribed and over-the-counter drug use, and alcohol use. Neurologic, muscular, perceptual defects and cardiovascular abnormalities are important contributors to falls and gait disorders directly and through interactions with the above conditions.

II. RESEARCH GOALS AND SCOPE

The goal of this RFA is to solicit research which will (1) determine the neurologic, muscular, perceptual, and cardiovascular factors in elderly people responsible for the various types of falls and disabling gait disorders and (2) elucidate the underlying pathophysiologic mechanisms. The long range purpose of the NIA is to develop the research base needed for future clinical trials of interventions to prevent falls and gait disorders.

Studies of interest include but are not limited to:

- A. Effects of neurologic and other chronic diseases of the elderly, and of medications widely used by the elderly, on gait and balance control mechanisms.
- B. Characterization of specific types of motor dysfunction responsible for postural instability, including deficits in strength and speed.

- C. Studies on dysfunctions in the speed or integration of reflexes involved in maintaining or regaining balance, including sensory pathways, central processing, or motor pathways.
- D. The effect of habitual physical activity or specific nutrients on the neuromuscular control of postural stability and gait.
- E. Studies on the contribution of abnormalities in vestibular function, proprioception, or visual spatial perception to the risk of falling.
- F. Autopsy or other pathologic studies of central or peripheral neurologic abnormalities, or muscle abnormalities, in persons with a high propensity to fall.
- G. The role of orthostatic hypotension in predisposing to falls.

III. MECHANISMS OF SUPPORT

The administrative and funding mechanisms to be used to support the studies will be the Research Project Award and the Program Project Award. The regulation (Code of Federal Regulations, Title 42, Part 52, and Title 45, Part 74) and policies that govern the research grant programs of the Public Health Service will prevail. The award of grants pursuant to this RFA is contingent upon the receipt of appropriated funds for this purpose. This RFA is a one time invitation. There are no plans for future reissuance. The duration of proposed projects may be up to five years. Renewal applications may be submitted but no funds have been specifically reserved for renewals at this time.

The start date for funded projects will be approximately July 1, 1986. A total of up to \$1,250,000 will be allocated to fund the first year awards. The number of awards will depend on the quality and research scope of approved applications.

IV. STAFF CONTACT

A letter of intent is not a prerequisite for applying; however, prospective applicants are encouraged to send a letter briefly describing scientific goals, staffing, subject population and resources of the proposed project. This letter should be sent to the NIA contact by August 15, 1985.

A complete RFA and additional information may be obtained from:

Teresa Sluss Radebaugh, Sc.D.
National Institute on Aging
Building 31 - Room 5C21
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: 301-496-1033

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-AI-06

MECHANISM OF LATENCY OF HERPES SIMPLEX VIRUS

P.T. 34; K.W. 1002045, 0765015, 0705055, 0760015

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application receipt date: November 15, 1985

I. BACKGROUND INFORMATION

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for a program project grant to be initiated during FY 1986 for participation in a program of research to define the mechanism of genetic regulation of latency and reactivation of herpes simplex virus in ganglionic nerve cells. This RFA will not be reissued in fiscal year 1986.

Herpes simplex virus (HSV) is ubiquitous in the populations of the world. Once infected an individual may present with mucocutaneous lesions and recover, but the virus usually persists for the life of the individual in a state of latency in neural ganglia or may periodically reactivate to cause recrudescence lesions.

Much of the morbidity associated with herpes simplex is related to the capacity of the virus to remain latent and to cause recrudescence lesions. None of the available drugs affect the virus in its latent state. Prophylactic use of acyclovir does not preclude recrudescence of lesions upon termination of treatment and continuous intake of the drug may pose more serious problems than the recurrences it suppresses.

Although it is known where the virus resides during the latent state, there is little data on the mechanism by which HSV establishes latency. Until recently, the methodology required to attack the problem was not available. The methodology currently available should be appropriate and sufficient to test current hypotheses regarding mechanism.

II. RESEARCH GOALS AND SCOPE

Specific program goals are listed as follows:

- A. Identify the genes and gene products controlling ascension of the HSV to the central nervous system.
- B. Detect latent gene products in cells of latently infected ganglia.
- C. Identify viral genes and gene products required to establish latency.

- D. Identify viral genes and gene products involved in the termination of latency.
- E. Identify ganglionic cell elements involved in both establishment and termination of latency.

The scope of the program shall be limited to mechanisms of latency and reactivation of herpes simplex virus, types 1 or 2, in man or in an appropriate animal model.

III. MECHANISM OF SUPPORT

Achievement of the stated goals requires multidisciplinary approaches with strong leadership for coordinating all aspects of the research. The program project grant mechanism is appropriate for these purposes. One program project can be awarded and supported for up to five years contingent upon the availability of funds. Renewability will depend upon progress toward the specific aims and the availability of funds.

Consortium agreements should be explored when all of the required expertise is not available in one institution. Domestic research laboratories of public or private institutions are eligible to apply.

Earliest possible start date is July 1, 1986. No currently funded projects are competing for renewal support under this announcement.

IV. IDENTIFICATION OF CONTACT POINT

Direct all inquiries and requests for the full text of the RFA to :

William P. Allen, Ph.D.
Bacteriology and Virology Branch
Westwood Building - Room 736
National Institute of Allergy and
Infectious Diseases
Bethesda, Maryland 20205

Telephone: (301) 496-7728

A more detailed RFA is available upon request from the Institute contact. A letter of intent, while not mandatory, is strongly suggested and should be forwarded to the Institute no later than September 3, 1985. A letter of intent is not binding and will not enter into the review of any application subsequently submitted.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-AI-07

SEXUALLY TRANSMITTED DISEASES RESEARCH UNITS

P.T. 34; K.W. 0715220, 0715125, 1002027, 1002032, 1002045, 0755020, 0785055, 0403004

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: November 15, 1985

I. BACKGROUND

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for a program project grant to be initiated during FY 1986 as part of a continuing program of research in Sexually Transmitted Diseases (STD). This RFA will not be reissued in fiscal year 1986.

One of the major health problems in the U.S. today is that of sexually transmitted (venereal) diseases. The explosive rise in gonococcal infections in the last decade, for example, with an estimated 2,000,000 gonococcal cases per year, can be considered a major infectious disease epidemic. Many other diseases, such as chlamydial infections and genital herpes also show similar increases. Enteric infections, hepatitis B, and cytomegalovirus are known to be transmitted by the sexual route; these are now being recognized with increasing frequency. Pelvic inflammatory disease, the most serious sequela of gonococcal and chlamydial infection in females, costs the Nation's health services an estimated \$1.25 billion annually.

II. RESEARCH GOALS AND SCOPE

- A. As one means of achieving the major goal of further needed research in this area, the NIAID proposes to maintain support of a number of STD Research Units, or centers of excellence, to serve as foci for research and training in STD. This RFA is for support of one such STD unit; these units are supported as multidisciplinary program project grants. A strong clinical component should be a major part of the application, with individual investigators heading separately identifiable research subprojects within the overall cover

This program is supported under authorization of the Public Health Service Act, Public Law 78-410, as amended. The Catalog of Federal Domestic Assistance citation is Sec. 13.856, Microbiology and Infectious Diseases Research. Awards will be administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

of the program project. The fields of research to be considered for emphasis in this program project can be on any or all of the STDs that are currently recognized as significant public health problems.

- B. The research efforts should focus on diseases known, or believed to be transmitted by sexual contact or the sexual route. The diseases of interest in this program are: gonorrhea; syphilis; chlamydial infection; trichomonas infection; viral infections such as genital herpes, genital warts, hepatitis B; nonspecific vaginitis; enteric diseases; parasitic infestations. Specific areas of research can include, but are not limited to: basic biology and virulence factors of the causal organisms, the hosts' immune responses; animal model systems; diagnosis, therapy, and preventive measures; epidemiology, including computer modeling studies.

An educational component to advance learning experiences in STD of medical staff and fellows, as well as a community outreach program, can be considered an appropriate part of the STD Research Unit.

This project will not, however, be considered for individual postdoctoral training; stipends for training are supported by other mechanisms.

C. MECHANISM OF SUPPORT

Eligibility - Domestic universities, medical colleges, hospitals, laboratories, and other public or private research institutions, including State and local governmental units, are eligible.

The program project (STD Research Unit) can be supported for up to five years; renewability is dependent on successful competition and the availability of funds. Earliest start date is August 1, 1986. This request is open to all applicants. Direct costs should not exceed \$450,000. One currently funded STD Research Unit will be competing for renewal support.

III. IDENTIFICATION OF CONTACT POINT

Direct all inquiries and requests for the full text of the RFA to:

Milton Puziss, Ph.D., Chief
Bacteriology and Virology Branch
MIDP
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 738
Bethesda, Maryland 20205

Telephone: (301) 496-7728

A more detailed RFA is available upon request from the Institute contact. A letter of intent, while not mandatory, is strongly suggested and should be forwarded to the Institute no later than September 15, 1985. A letter of intent is not binding. It will not enter into the review of any application subsequently submitted and is not a necessary requirement for application.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-06

DEVELOPMENT, VALIDATION AND APPLICATION OF BIOCHEMICAL MARKERS OF
HUMAN EXPOSURE FOR USE IN EPIDEMIOLOGIC STUDIES

P.T. 34; K.W. 0715035, 0785055

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: October 1, 1985
Application Receipt Date: November 4, 1985
Start Date: July 1, 1986

The Division of Cancer Etiology (DCE), National Cancer Institute (NCI), invites applications for cooperative agreements to further the effective use of biochemical markers as exposure indices in future epidemiologic studies. Although the awards will be made and managed by the NCI, staff involvement and participation in funding on the part of the National Institute for Occupational Safety and Health (NIOSH), the National Institute of Environmental Health Sciences (NIEHS) and the Environmental Protection Agency (EPA) is anticipated.

The purpose of this announcement is to solicit applications directed toward the further development of biochemical markers of exposure to increase the power of epidemiologic studies in which they can be utilized. It is expected that positive results would be widely applied by the epidemiologic research community in the design of future studies.

The specific objective of the initiative is to encourage investigations designed to develop, characterize, validate and apply measurement methods for biologic markers of human exposure (which has occurred in the recent or distant past) which would be useful in the conduct of epidemiologic studies.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between federal staff and the awardees to accomplish the purpose of the activity. As more completely described in the RFA, the recipients will be totally responsible for the development and conduct of the research. Involvement of staff members of the Federal organizations specified above will be non-directive and will not, under any circumstance, control the research activities to be carried out. It will be limited to 1) consulting on proposed methodologies to maximize their epidemiologic utility, 2) providing a resource of information on the extent and distribution of exposures, 3) providing information on, and access to, cohorts of exposed individuals which could provide material for methods development and validation, and 4) facilitating the exchange of information and materials among the awardees. Non-profit and for-profit organizations and institutions may apply. All applications submitted in response to this announcement will be classified as new grants (Type 1).

Copies of the complete Request for Applications and additional information may be obtained from:

John A. Cooper II, Ph.D.
Extramural Programs Branch
Landow Building - Room 8C16
National Cancer Institute
Bethesda, Maryland 20205

Telephone: (301) 496-1882

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HD-12

RESEARCH ON TEEN CONTRACEPTIVE BEHAVIOR

P.T. 34; K.W. 0775020, 0750020, 0413002, 0403001, 0404000

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: November 15, 1985

BACKGROUND INFORMATION

The Demographic and Behavioral Sciences Branch (DBSB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD), supports research on the antecedents and consequences of adolescent pregnancy, contraception, and childbearing. This RFA invites scientists to submit grant applications for the support of research on an important aspect of adolescent fertility, the factors affecting the ability of sexually active teenagers to contracept effectively.

Research documents that one of the main reasons teen fertility in the United States is high (relative to other developed countries) is inadequate or ineffective contraceptive use among sexually active teenagers. A number of research studies have found, particularly among young female teens, failure to use contraception at first intercourse and during the first year after first intercourse. As a result, the risk of pregnancy is very high during this period. Although contraceptive use gradually improves, there is still a substantial failure rate among contraceptors. Use-effectiveness rates among female teens are much lower than those among older women. Almost nothing is known about teen male contraceptive behavior. A number of hypotheses have been advanced to explain teen contraceptive behavior. Some focus on individual factors: ambivalence about one's sexuality, lack of knowledge of the risk of pregnancy, substance use/abuse, inability to plan ahead, cognitive immaturity, low aspirations, inadequate motivation to avoid pregnancy; on couple factors: inability to communicate, embarrassment, failure for one person to take responsibility; on community factors: lack of accessible, appropriate and affordable family planning methods/services, lack of meaningful alternatives to childbearing; and on societal factors: lack of contraceptive advertising, and ambivalent societal attitudes about sexuality and contraception.

The purpose of the proposed research would be to test some of the hypotheses advanced to explain use and non-use of contraception, the process of contraceptive adoption, patterns of use between first intercourse and regular use, the effectiveness of use, and the choice of methods among teenagers. Researchers would be encouraged to conduct research on males as well as females. Although researchers would be expected to focus on adolescents and their behavior, contraceptive use cannot be interpreted as a uniquely adolescent problem unless their behavior is compared with that of comparable older individuals. Thus researchers may wish to have a comparison group of older women and/or men. The results of this research will complement planned research on

contraception among adults and ongoing research on the consequences of pregnancy resolution decisions, as well as help fill out the gaps in our understanding of teen fertility behavior in general.

MECHANISM OF SUPPORT

The support mechanisms for this program will be the individual research project grant and the New Investigator Research Award (NIRA).

Copies of the complete RFA may be obtained from:

Sandra L. Hofferth, Ph.D.
Demographic and Behavioral Sciences Branch
National Institute of Child Health
and Human Development
Landow Building - Room 7C25,
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1174

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

85-HD-13

COOPERATIVE MULTICENTER PROGRAM ON ENVIRONMENTAL CONDITIONS FOR
NON-HUMAN IN VITRO FERTILIZATION AND PREIMPLANTATION DEVELOPMENT

P.T. 34; K.W. 1002042, 1002017, 0780020, 0780015, 1002052

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: October 15, 1985

The National Institute of Child Health and Human Development (NICHD) invites applications from investigators willing to participate with the NICHD under a Cooperative Multicenter Program funded by cooperative agreements and designed to determine the environmental conditions that will promote more effective non-human in vitro fertilization and especially, more successful, normal in vitro preimplantation development for several species. The Institute program staff will cooperate with the Principal Investigators in planning and evaluation of the research and serve as coordinator, facilitator and partner in the research. The research will consist of:

- Phase I (3 months) - Determination, by consensus, of experimental approaches, design of protocol, methods of standardization of experiments between centers, determination of experimental end points and methods of evaluation, statistics;
- Phase II (45 months) - Determination and testing of culture media formulations, gas phases and culture vessels for non-human in vitro fertilization and preimplantation development;
- Phase III (12 months) - Analysis and dissemination of results to be done as various segments of the research are completed.

This program is described in the Catalog of Federal Domestic Assistance No. 13.864 Population Research. Awards will be made under authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review

It is anticipated that there will be substantial evolution of the program as new findings are obtained and shared. New principles obtained from research on one species could be rapidly tested in other species. Applications received after the receipt date will not be considered. Only institutions in the United States will be eligible for participation.

MECHANISM OF SUPPORT:

The funding mechanism for assistance in this high priority area of research will be cooperative agreements between the participating units and NICHD. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of NICHD staff above and beyond conventional grants management procedures.

APPLICATION PROCEDURE:

Potential applicants can request further information and copies of the full RFA which outlines the requirements for participation in this program from:

Richard J. Tasca, Ph.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - Room 7C-33
Bethesda, Maryland 20205

Telephone: (301) 496-651

ANNOUNCEMENT

MULTIDISCIPLINARY RESEARCH CENTER(S) FOR THE STUDY OF NEURO-GENETIC
DISORDERS OF INFANCY AND CHILDHOOD

P.T. 04; K.W. 0705055, 1002019, 0715135, 0785165, 0403020, 0770005, 0755030, 0745020,
0415000

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND
STROKE

The Convulsive, Developmental, and Neuromuscular Disorders Program of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) encourages the submission of research center grant applications (P50) to establish one or more multidisciplinary research centers for the purpose of investigating epidemiologic, genetic, biochemical and clinical aspects of neuro-genetic disorders of infancy and childhood and of developing measures for their prevention, early diagnosis and treatment.

I. BACKGROUND

It is estimated that of the 3,000 known genetic disorders, as many as one-third are primarily neurologic or have important neurologic involvement. Most of them occur with low frequencies, but collectively they impose an enormous burden on the family and on society. Examples of such disorders that affect infants or children are: neurofibromatosis, tuberous sclerosis, infantile and juvenile types of neuronal ceroid lipofuscinosis (Jansky-Bielschowsky disease, Batten disease), adrenoleukodystrophy, neuroaxonal dystrophy, Pelizaeus-Merzbacher disease, trichopoliodystrophy, and subacute necrotizing encephalopathy (Leigh disease). Most of these neuro-genetic disorders show a Mendelian pattern of inheritance. Some disorders, however, also occur sporadically and their genetic basis is not clear. The metabolic defects in neuro-genetic disorders are largely unknown. Because of the low frequency of individual disorders, in-depth studies may encounter many technical and logistic difficulties. The proposed multidisciplinary research center(s) should provide the necessary expertise in a suitable milieu where a spectrum of these neuro-genetic disorders can be investigated.

II. RESEARCH GOALS AND SCOPE

Through the research center grant activity, the NINCDS intends to fund one or more multidisciplinary centers where the scope of research may include both basic and clinical investigations into the etiology, pathogenesis, diagnosis, prevention and

This program is described in the Catalog of Federal Domestic Assistance No. 13.852, Neurological Disorders. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

therapy of neuro-genetic disorders of infancy and childhood, particularly those which occur with low frequency and whose metabolic defect is unknown. Investigators are encouraged to assemble multidisciplinary expertise in these areas to conduct research employing a variety of experimental approaches and methods. Consortium agreements are encouraged to provide access to suitable patient populations. Some examples are given below, but these are not limiting.

- A. Subjects. Studies on patients and their families are encouraged. However, the development of animal models, particularly homologous mutants, would greatly facilitate research and would provide direct and crucial information about the etiology and pathogenesis of these disorders.
- B. Clinicopathologic correlations. The relation of the clinical picture to pathologic findings is a most important aspect of this research. Histopathologic studies, including neurochemical studies of fresh tissue, should provide basic data for better understanding of the relationship between pathophysiology and the evolution of clinical signs and symptoms, as well as the course of the disorder.
- C. Genetics. Classical genetic studies have established the mode of inheritance for most of these disorders. Further genetic studies, however, using modern, precise methods are needed to determine if etiologic heterogeneity exists, and if sporadic cases are due to reduced penetrance or represent phenocopies. A most important contribution of genetic studies would be to establish the chromosomal location and linkage relationships of the genes responsible for these disorders. State of the art methodologies for such studies should be used, including cell hybridization and restriction fragment length polymorphisms.
- D. Biochemistry. Studies should be directed at discovering the metabolic defect in each of these disorders and identifying its molecular basis. Successful biochemical studies will lead to understanding of the pathogenetic mechanisms and make possible the recognition of the heterozygote. Currently available advanced and sophisticated methodologies should be brought to bear on this important research, including monoclonal antibody technology, the highly sensitive techniques of histochemistry, immunochemistry and membrane microchemistry, tissue culture, and the high-resolving power of rapid flow microfluorimetry and two-dimensional electrophoresis.
- E. Neuroimaging. New neuroimaging technologies provide investigators with opportunities in the study of neuro-genetic disorders. When infants with serious neuro-genetic disorders undergo diagnostic procedures for their own medical benefit, an opportunity may be present for intensive study of brain pathology and function not permissible in infants and children with less serious disorders.

III. ETHICAL ISSUES

Some specific research projects on neuro-genetic disorders may present complex ethical issues. In such instances, applicants are expected to include a thorough and precise discussion of specific ethical issues as they relate to the given project.

IV. MECHANISM OF SUPPORT

Support for this program will be through the traditional grant-in-aid. Successful applicants will direct and carry out the center's research projects.

V. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on Form PHS 398 according to instructions contained in the application kit which is available from most institutional business offices, or from the Division of Research Grants (DRG), at the address given below. NINCDS "Guidelines for Research Center and Program Project Grants" must be followed and are available from staff listed in item V. Check "Yes" in item 2 on the face sheet of the application and type **"RESEARCH CENTER FOR THE STUDY OF NEURO-GENETIC DISORDERS OF INFANCY AND CHILDHOOD"** in the space provided.

To be noted: The NINCDS has a \$600,000 per year maximum direct cost guideline on any award action. Contact program staff for additional information -- see item V.

The original and six copies of the application should be mailed to the following address:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Deadline dates for the receipt of center research grant (P50) applications are October 1, February 1, and June 1.

For further information applicants may contact:

Dr. Ntinos C. Myrianthopoulos
National Institute of Neurological and Communicative
Disorders and Stroke
National Institutes of Health
Federal Building - Room 8C-16A
Bethesda, Maryland 20205

Telephone: (301) 496-5821

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

COOPERATIVE AGREEMENTS FOR NATIONAL COLLABORATIVE CHEMOPREVENTION PROJECTS

85-CA-15

P.T. 34; K.W. 0715035, 0745055, 0760035

NATIONAL CANCER INSTITUTE

Application Receipt Date: October 25, 1985

The Division of Cancer Etiology (DCE) of the National Cancer Institute (NCI) invites applications for cooperative agreements for NATIONAL COLLABORATIVE CHEMOPREVENTION PROJECTS (NCCP). The projects are conceived as new approaches to cancer prevention in order to: acquire basic knowledge in significant biological systems for carcinogenesis/anticarcinogenesis; derive new insights into practical means for chemoprevention of the carcinogenic process; and rapidly translate these understandings into new chemopreventive entities with known ranges of efficacy and defined pharmacologic/toxicologic properties.

The present RFA announcement is for a single competition with a specified deadline of October 25, 1985 for receipt of applications.

I. BACKGROUND

The DCE has responsibility for support of basic research and development efforts in chemoprevention of cancer. As a program mechanism in addition to individual grants and contracts, the new projects are envisioned as means to enhance and expand multidisciplinary/interdisciplinary basic studies in development of new chemopreventive entities and strategies for cancer prevention. Each NCCP would consist of a number of laboratory research programs representing diverse scientific disciplines and expertise. Scientists in a given project could derive from any combination of the academic, non-profit, and for-profit communities. Scientists in an NCCP could also be drawn from a single organization possessing necessary diversity and in-depth expertise to accomplish project objectives. Each project is envisioned to consist of a project Director, Program Leaders in several broad scientific disciplines and an NCI Coordinator. The project Director has the responsibility for organizing the project, assembling the multidisciplinary group of Program Leaders, preparing the cooperative agreement application and serving as Principal Investigator. This individual provides scientific and administrative leadership and, in addition, is expected to provide a laboratory program. A high degree of interaction and focus are expected in project efforts.

Many classes of chemopreventive agents have been investigated in numerous biological systems, and of these, a significant number appear promising for substantial developmental efforts. These classes include, among others, protease inhibitors, antioxidants, dithiolthiones, dehydroepiandrosterone and related analogs, cyanates and isothiocyanates, inhibitors of arachidonic acid metabolism, nucleophiles and potential new classes of inhibitors existing in natural products such as foods consumed by man, as exemplified by green and yellow vegetables. Since there is already extensive activity in retinoids research and development, applications in this area will be considered non-responsive.

II. MECHANISM OF SUPPORT

Awards will be made as Cooperative Agreements. These are assistance relationships involving substantial involvement of NCI staff during performance of the project. The nature of NCI staff participation is included in the RFA. However, the applying project must define its objectives in accord with its own interests and perceptions of novel approaches to cancer prevention. The role of NCI staff will be to provide assistance, advice and guidance after an award is made. Final decision-making authority during performance will rest with the project director.

NCI anticipates the funding of multiple awards for project periods of five (5) years and has set aside \$1,500,000 for the initial year's funding. The expected starting date for these awards is August 1, 1986. Although this program is provided for in the financial plans of the NCI, awards are contingent upon availability of funds for this purpose and the receipt of applications of high scientific merit.

III. INQUIRIES

The RFA is available from:

Carl E. Smith, Ph.D.
Program Director
Biological and Chemical Prevention
Chemical and Physical Carcinogenesis Program
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 9B-06
Bethesda, Maryland 20205

Telephone: (301) 496-4141



NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 14, No. 11, October 11, 1985

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Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

RESEARCH TRAINING OF NURSES

P.T. 44; K.W. 0720005, 0785130

This notice calls the attention of National Research Service Award (NRSA) training program directors seeking highly qualified applicants for trainee appointments to the fact that there is a recruitment pool in the nurse community which may have been overlooked.

In May 1984, Dr. James Wyngaarden, Director, NIH, appointed an NIH Task Force charged with reviewing NIH activities involving nursing research. Recommendations made by the Task Force in its final report included several relative to the research training of nurses. In particular, it was noted that many nurse graduates with baccalaureate and doctoral degrees were unaware that they may be eligible to apply for appointments as predoctoral or postdoctoral trainees on NRSA institutional training grants or as applicants for individual NRSA fellowships.

NIH is taking steps to acquaint the nursing community with the eligibility requirements for these programs and the locations and names of the program directors of Institutional NRSAs. NRSA training program directors should also make information about their programs available to the nursing profession.

NOTICE

NURSE SCIENTISTS SOUGHT FOR INITIAL REVIEW GROUPS

P.T. 22, 34; K.W. 0710030, 0720005

DIVISION OF RESEARCH GRANTS (NIH)

The National Institutes of Health (NIH) encourages and welcomes the submission of names of nurse scientists with research experience as potential members of the various initial review groups (study sections) that carry out the review of grant applications for the support of research and training. Names and curricula vitae should be sent to:

Mischa E. Friedman, Ph.D.
Chief, Referral and Review Branch
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20892

NOTICE**MULTIPURPOSE ARTHRITIS CENTERS**

P.T. 34; K.W. 0715010, 0785195, 0705050, 0403004, 0500000

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) supports a series of Multipurpose Arthritis Centers through the Comprehensive Research Center grant mechanism (P60). In a recent notice (NIH Guide for Grants and Contracts, Vol. 14, No. 7, June 21, 1985) the NIADDK fixed the length of project periods for all centers at five years, except under unusual circumstances.

In accord with this policy, the Multipurpose Arthritis Center Program announces two changes in its Application Guidelines:

1. Developmental and feasibility study support will, subject to the recommendations of the Initial Review Group, now be provided for the full five year period of award, based on the number and quality of the approved studies.
2. The present three-component structure of the Multipurpose Arthritis Centers (Research, Education, and Community/Health Services Research components) will be changed to two components. The first component will be biomedical research. The second component will encompass the Education and Community/Health Services Research Components. Applicants will, accordingly, propose a full five-year program for each of the two components.

These changes become effective immediately. Questions regarding these changes and requests for the addendum to the Application Guidelines should be directed to:

Dr. Steven J. Hausman
Director, Multipurpose Arthritis
Centers Program
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building - Room 403
Bethesda, Maryland 20892

Telephone: (301) 496-7495

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-CA-01

CANCER CONTROL TECHNICAL DEVELOPMENT IN HEALTH AGENCIES

P.T. 34; K.W. 0715035, 0730070, 0403004

NATIONAL CANCER INSTITUTE

Application Receipt Date: January 15, 1986

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites grant applications to enhance the technical capabilities of health agencies in cancer prevention and control.

RESEARCH GOALS AND SCOPE

The goal of this RFA is to enable health agencies at State or selected local levels to enhance their capacity to plan, implement and evaluate cancer control programs. NCI support will provide for access to technical expertise in needs assessment, prioritization, program planning and evaluation. Health agencies are expected to provide for funding of any implementation and operation of resulting cancer control programs.

ELIGIBILITY

Applicant must be a State, territorial or local public health department or other agency designated by, operated by or under contract with a State, territorial or local government, with primary cancer control responsibility for a population of at least 500,000. An applicant other than a health department must demonstrate the direct involvement of a health department in the application. Applications that include more than one jurisdiction to meet minimum population requirements will be accepted.

MECHANISM OF SUPPORT

Awards will be made as grants. Funding is limited to a maximum of five years. Between 5-10 awards are anticipated depending on the availability of quality applications and funding.

INQUIRIES

Copies of the complete RFA and additional information may be obtained from:

Dr. Lawrence Bergner, Program Director
Cancer Control Applications Branch
Science Program, Division of Cancer Prevention
& Control
National Cancer Institute
Blair Building - Room 4A01
9000 Rockville Pike
Bethesda, Maryland 20892-4200
Telephone: (301) 427-8597

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****86-HD-01****TROPHECTODERM/BLASTULA DEVELOPMENT**

P.T. 34; K.W. 0413002, 1002059, 1002019, 1002008

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: February 18, 1986

The Reproductive Sciences Branch (RSB), of the Center for Population Research (CPR), of the National Institute of Child Health and Human Development (NICHD), announces the availability of a Request for Applications (RFA) on trophectoderm/blastula development. The purpose of this program is to encourage and support research on genetic, biochemical, biophysical, morphological and molecular biological approaches to the problem of the formation of the animal egg into the first epithelium, referred to as the trophectoderm in mammals and the blastula in non-mammals. The fact that trophectoderm formation is the predominant activity of preimplantation development underscores its importance to mammalian reproduction. This genetic and epigenetic emphasis on trophectoderm/blastula development is part of an RSB program on the developmental biology of reproduction that encompasses gametogenesis through implantation research. This initiative is a critical aspect of the mission of the RSB to provide a research base for improved understanding of human and animal reproduction with implications for the control of fertility and infertility.

This program will be funded through the individual research project grant mechanism. Grant applications will be reviewed at a single competition by an initial review group convened by NICHD. It is anticipated that 8-10 grants will be awarded contingent on scientific merit and availability of funds.

Requests for copies of the full RFA should be addressed to:

Richard J. Tasca, Ph.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building - Room 7C33
Bethesda, Maryland 20892

Telephone: (301) 496-6515

This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: (RFA)

86-AM-01

KIDNEY AND UROLOGICAL RESEARCH CENTERS

P.T. 04; K.W. 0785055, 0785095, 0785220, 0705030, 0705075, 0715135, 0755030,
1002004, 1002008, 1002019, 0785035

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Application Receipt Date: March 15, 1986

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK) announces a national competition to encourage the submission of research center applications (P50), which will establish a limited number of Kidney and Urological Research Centers for the purpose of investigating the epidemiology, causes, prevention and treatment of kidney and urinary tract disorders.

I. BACKGROUND

Kidney and urologic diseases account for substantial and increasing morbidity and financial burden in the United States; cumulatively they are responsible for a large number of work days lost and the loss of all or a part of a normal healthy life. Although considerable progress has been made in understanding the basic physiology and pathophysiology of the normal renal and urologic system, there has been little progress in the understanding of fundamental disease processes. Nevertheless, major progress has been made in the management of the clinical sequelae of these diseases. For example, renal dialysis and transplantation have been developed as life-saving procedures and the surgical management of benign prostatic hyperplasia (BPH) has also made substantial progress over the past twenty years. Unfortunately, these advances are not curative procedures and are costly. The proposed multidisciplinary research centers should provide appropriate expertise to investigate the topical areas of immunologically mediated diseases; diabetes mellitus and other endocrine and metabolic disorders; primary renal hypertension; genetic abnormalities; developmental and obstructive disorders; nephrotoxins and toxic cell injury.

This program is described in the Catalog of Federal Domestic Assistance No. 13.849, Kidney, Urologic, and Hematologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

II. RESEARCH GOALS AND SCOPE

The emphases of this initiative are threefold: (1) to attract new scientific expertise into the study of the basic mechanisms of kidney and urological diseases; (2) to encourage interdisciplinary research; and (3) to extend these basic investigations into innovative clinical and epidemiologic studies of the causes, therapy and prevention of kidney and urologic disorders. In approaching one or more of the disease processes outlined above, it is anticipated that extensive collaboration will be required between individuals in the basic sciences, including cell biology, molecular biology, immunology, genetics, epidemiology, biochemistry, physiology and pathology with clinical sciences. Thus it is an express intent to engage into the the field investigators not currently active in renal and urinary tract research and to explore new basic areas which may then be applied to clinical research projects. Individual institutions with both basic and clinical research capabilities would qualify for applying; however, the arrangement for inter-institutional collaborative research activities is another means of meeting the intent of this announcement. It is anticipated that initially NIADDK will fund six Centers at a level not to exceed \$1.0M/year/Center including indirect costs. These awards will be made for five years and the progress of each Center will be evaluated annually.

III. MECHANISM OF SUPPORT

Support for this program will be through the traditional grant-in-aid. Successful applicants will direct and carry out the center's research projects.

IV. APPLICATION AND REVIEW PROCEDURES

The applications for Centers solicited in this announcement will be evaluated in national competition by a special review committee convened by the NIADDK. Deadline for the receipt of the applications will be March 15, 1986 and letter of intent should be received from all prospective applicants by the close of business on January 15, 1986.

V. INQUIRIES

Potential applicants may request additional information and copies of the entire RFA from:

M. J. Scherbenske, PH.D.
Assistant to the Director for Administration
Renal Physiology/Pathophysiology Program Director
DKUHD/NIADDK
Westwood Building - Room 621
5333 Westbard Avenue
Bethesda, Maryland 20892

ANNOUNCEMENT

AVAILABILITY OF REQUESTS FOR APPLICATIONS: (RFA)

86-HL-01-B

HEMOSTATIC DEFECTS IN RENAL FAILURE: PATHOGENESIS AND TREATMENT

P.T. 34; K.W. 0785070, 0785095, 0785165

DIVISION OF BLOOD DISEASES AND RESOURCES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 18, 1986

The Blood Diseases Branch of the Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

The program will support research addressing the hemostatic defect observed in some patients with chronic renal failure. The scope of this program includes identification of factors responsible for the bleeding tendency and development and evaluation of possible therapeutic interventions to correct such hemostatic defects. The long range goal of this activity is to expand the knowledge base on hemostatic mechanisms.

Awards in response to this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

Requests for copies of the RFA should be addressed to:

Carol H. Letendre, Ph.D.
Division of Blood Diseases and Resources
Federal Building - Room 5A12
7550 Wisconsin Avenue
Bethesda, Maryland 20892

Telephone: (301) 496-5911

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: (RFA)****85-HL-02-B****MEMBRANE TRANSPORT, PERMEABILITY AND VOLUME CONTROL IN SICKLE CELL DISEASE**

P.T. 34; K.W. 0790005, 0785070, 0715040

DIVISION OF BLOOD DISEASES AND RESOURCES**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Date: February 18, 1986

The Sickle Cell Disease Branch, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above mentioned subject. Copies of the RFA, 86-HL-2-B, may be obtained from the staff of the NHLBI.

The purpose of this program is to encourage research on the red cell membrane with relation to transport, permeability, and volume control in sickle cell disease. Studies have shown that sickle cell disease involves alterations of the erythrocyte membrane and that the sickling phenomenon is accompanied by decreased membrane deformability. This research would provide innovative approaches to elucidate the role of the erythrocyte membrane in hemoglobin S gelation and ultimately to apply this knowledge to the development of therapeutic approaches for sickle cell disease. Awards in response to this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

Requests for copies of the RFA should be addressed to:

John I. Hercules, Ph.D
Sickle Cell Disease Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 508A
Bethesda, Maryland 20892

Telephone (301) 496-6931

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-HL-03-L

DEVELOPMENT AND DIFFERENTIATION OF AIRWAY EPITHELIUM

P.T. 34; K.W. 0705065, 1002059, 1002004, 1003002, 0765035, 0710100

DIVISION OF LUNG DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1986

The Structure and Function Branch of the Division of Lung Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a request for applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will support basic research on the cellular and molecular mechanisms that influence and regulate development of epithelial cells in normal prenatal and early postnatal lung. It is expected that research applications will encompass a variety of approaches (morphologic, biochemical, molecular, etc.) and will require expertise from a wide variety of disciplines including cell biology, biochemistry, pathology, and pharmacology.

A letter of intent is requested by February 15, 1986, and the deadline for receipt of applications is April 1, 1986. The earliest award date for successful applications will be in September, 1986. Awards in response to this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

Requests for copies of this RFA should be addressed to:

Dorothy Berlin Gail, Ph.D.
Chief, Structure and Function Branch
Division of Lung Diseases, NHLBI
5333 Westbard Avenue - Room 6A07
Bethesda, Maryland 20892

Telephone: (301) 496-7171

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-HL-04-H

FUNDAMENTAL STUDIES OF CARDIAC MORPHOGENESIS

P.T. 34; K.W. 0705015, 1002059, 0710030

DIVISION OF HEART AND VASCULAR DISEASES NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: March 15, 1986

The Cardiac Functions Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject.

This program will support interdisciplinary research on fundamental mechanisms which underlie normal development of the heart. The emphasis of the program is on the interplay of developmental processes, particularly in terms of structure/function relationships.

This announcement may be of particular interest to investigators with expertise in anatomy, biochemistry, biomedical engineering, biology, biophysics, computer modelling, embryology, genetics, microscopy, molecular biology, pathology, pediatric cardiology, pharmacology, and physiology. Awards in response to this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

TIMETABLE

Letter of Intent	December 31, 1985
Application Receipt Date	March 15, 1986
Technical Review	May-June 1986
Advisory Council Review	September 11-12, 1986
Award Date	September 1986

INQUIRIES

Inquiries concerning this program and requests for copies of the RFA should be addressed to:

Constance Weinstein, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 304
7550 Wisconsin Avenue
Bethesda, Maryland 20892

Telephone: (301) 496-1627

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: (RFA)

86-HL-06-H

BIOLOGICAL MECHANISMS OF NUTRIENT EFFECTS ON BLOOD PRESSURE

P.T. 34; K.W. 0705015, 0715115, 1002034, 1002004, 1002008, 0710100, 1003002, 0710095

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 1, 1986

The Hypertension and Kidney Diseases Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a request for applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will support basic and clinical research designed to elucidate the mechanism or mechanisms by which nutrients affect blood pressure. It is expected that the applications will encompass a variety of approaches (humoral, vascular, biochemical, molecular, etc.). Numerous basic and clinical disciplines are applicable, including physiology, cell biology, molecular biology, pharmacology, biochemistry and clinical nutrition. Awards in response to this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

Requests for copies of the RFA should be addressed to:

John B. Dunbar, Dr. P.H.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4C10
Bethesda, Maryland 20892

Telephone: (301) 496-1857

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-HL-09-P

PHYSICAL ACTIVITY AND FITNESS ASSESSMENT METHODS

P.T. 34; K.W. 0785055, 0755015, 0745030, 0404021, 0735015, 0745020

DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: February 18, 1986

The Epidemiology and Biometry Program of the Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

The special grant program will support research investigating physical activity and fitness measurement methods for use in epidemiological and clinical trials research. Three general areas have been identified that could be addressed by grant applications:

1. Validation and reproducibility of current physical activity and/or fitness questionnaires or other measures for epidemiological and clinical trials research.
2. Validation of movement sensors or other devices for objective measurement.
3. Development of blood or other biological markers of recent past or current physical activity and fitness status.

Awards in response to this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

Requests for copies of the RFA should be addressed to:

Dr. Richard Donahue
Epidemiology and Biometry Program
National Heart, Lung, and Blood Institute
Federal Building - Room 2C08
Bethesda, Maryland 20892

Telephone: (301) 496-2327

ANNOUNCEMENT

BIOMEDICAL RESEARCH SUPPORT GRANT APPLICATIONS FOR FISCAL YEAR 1986

P.T. 34; K.W. 0710030

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: January 2, 1986

I. BACKGROUND

The Biomedical Research Support Grant (BRSG) Program is designed to provide funds to eligible institutions (i.e., those heavily engaged in health-related research) to strengthen their programs by allowing flexibility to meet emerging opportunities in research; to explore new and unorthodox ideas; and to use these research funds in ways and for purposes which, in the judgment of the grantee institution, would contribute most effectively to the furtherance of their research program.

II. ELIGIBILITY

Awards are made to non-profit institutions, not directly to individual investigators. Health professional schools, other academic institutions, hospitals, state and municipal health agencies, and research organizations may apply if during FY 1985 (October 1, 1984 through September 30, 1985) the institution was awarded a minimum of three allowable PHS biomedical or health-related behavioral research grants, totaling \$200,000 (including direct and indirect costs). Federal institutions and institutions located in a foreign country are not eligible.

NOTE: Other academic includes, as a single eligible component, all other schools, departments, colleges and free-standing institutes of the institution except the health professional schools.

III. AWARD CONDITIONS

The BRSG award is for one year and must be renewed annually. The start date is April 1. It is estimated that approximately 556 BRSG awards will be made in FY 1986.

This program is described in the catalog of Federal Domestic Assistance, No. 13.337, Biomedical Research Support. Grants will be awarded under the authority of the Public Health Service Act, Section 301 (a)(3); Public Law 86-798, (42 USC 241) and administered under PHS grant policies and Federal Regulations 45 CFR Part 74 and the Biomedical Research Support Grant Information Statement and Administrative Guidelines. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The amount of each BRSG award is based upon a formula that is applied to the total of direct and indirect costs awarded for allowable PHS research grants.

IV. METHOD OF APPLYING

BRSG application kits (Form NIH-147-1) will be mailed on or about November 26 to institutions that, according to NIH records, are eligible to apply for a BRSG.

Completed BRSG applications must be received by January 2, 1986. If an institution believes that it is eligible and has not received an application kit by December 5, 1985, please submit a letter of request to:

Mrs. Gilda Polletto
Grants Management Specialist
Office of Grants and Contracts Management Division of
Research Resources
National Institutes of Health
Building 31 - Room 5B-32
9000 Rockville Pike
Bethesda, Maryland 20892

ANNOUNCEMENT

**COMBINED IN VIVO APPLICATION OF MULTINUCLEAR MAGNETIC RESONANCE
IMAGING AND SPECTROSCOPY**

P.T. 34; K.W. 0706030, 0745020, 0715035, 0735015, 1003001, 0785190

NATIONAL CANCER INSTITUTE

Initial Application Receipt Date: November 1, 1985
Subsequent Application Receipt Dates: February 1, June 1, October 1

The Radiation Research Program (RRP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI) supports a variety of research programs in the area of medical imaging for the diagnosis and treatment of cancer. The present program announcement is to encourage the submission of scientifically meritorious grant applications in the specific area of magnetic resonance. The RRP anticipates that the described research can be completed in a period of three to four years and depending on the nature of the awarded projects, renewal applications may be considered.

The pressing need for accurate noninvasive cancer diagnosis mandated this initiative. This announcement is to emphasize the continuing interest of the Diagnostic Imaging Research Branch (DIRB), RRP, DCT, NCI in innovative research in magnetic resonance imaging (MRI) and encourages the submission of applications leading to the advancement and improvement of the state-of-the-art in this important area of cancer diagnosis and tumor monitoring.

The major thrust in magnetic resonance imaging has been in the direction of visualizing the resonating hydrogen nucleus (proton imaging), there being an abundant supply of hydrogen in the body, chiefly in water, but also in various tissues. The intrinsic differences in proton relaxation times between fluid, fat, muscle, blood, tumor and bone are major determinants of the contrast available for use in proton imaging.

Recent research in MRI shows that nuclei other than hydrogen have been visualized by using higher magnetic field strength plus receiver coils tuned for the specific Larmor frequency. For example, visualization of sodium nuclei, which appear to be in greater concentration in gliomas than in surrounding brain, has been achieved. The phosphorus nucleus has also been visualized, but because of the relatively small amount of phosphorus in tissue, this imaging does not at this time have the clarity of the proton image.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Using magnetic resonance spectroscopy murine tumors have been found to exhibit significant change in their in vivo ^{31}P phosphorus spectra at various stages of growth and in response to various forms of therapy. Preliminary experiments suggest that regional changes in blood flow and pH (using ^{19}F , ^{31}P) may be documented in localized tumors by combining imaging and spectroscopic methods. Imaging results with ^{31}P have demonstrated the ability to spatially localize regional ATP, ADP, inorganic phosphate and phosphocreatine, all of which may prove to be indicators of responsiveness versus resistance of tumor. Using phosphorus spectroscopy, researchers have been able to differentiate human small cell from non-small cell carcinoma of the lung. Other tumors that have been differentiated spectroscopically are human neuroblastoma and breast cancer.

This announcement encourages research with the combined in vivo applications of multinuclear MRI and MRS for increasing sensitivity of tumor demonstration spatially and monitoring of biochemical response to therapy by spectroscopic methodology. Special areas of interest specifically identified are:

1. Combined in vivo multinuclear research in MR imaging and spectroscopy.
2. Correlation of magnetic resonance images with spectroscopic biochemical analysis in normal and abnormal tissue, that is, following steady state responses to different interventions by following metabolites.
3. Correlation of magnetic resonance imaging with biochemical and metabolic changes associated with tumor responses to chemotherapy and radiotherapy; determination of response to and distribution of drugs, and response to radiotherapy by evaluating regional differences in tumor using surface coil spectroscopy and imaging.
4. Evaluation of steady state metabolic changes occurring in specific areas of local tumor masses by spatial demonstration of various parts of the tumor mass (MRI) and by multinuclear studies (MRS) for the measurement of steady state bioenergetics (^{31}P), and glycolytic pathways (^{13}C , ^1H) and by determination of regional blood flow and pH effects (^{31}P , ^{19}F).
5. Determination of the clinical applications of the combined biochemical response and imaging correlates of neoplastic tissue.
6. Determination of spectroscopic data by both invasive and non-invasive techniques. Data may be acquired by local surface coil versus shaped, depth correlated RF pulses.
7. Contrast enhancement studies based on multinuclear imaging, paramagnetic contrast agents and chemical shift imaging to localize and delineate tumor (MRI) and concurrent evaluation of biochemical properties (MRS) in an attempt at tissue characterization.
8. Other areas of pertinent investigation in combined MRI and MRS research inadvertently omitted in this announcement would be appropriate to this program.

ELIGIBILITY

Non-profit organizations and institutions, governments and their agencies, for profit organizations, and individuals are eligible to apply.

REVIEW PROCEDURES AND CRITERIA

Applications should be submitted on form (PHS-398-Rev 5/82) which is available in the institution's collaborative research or business office. Otherwise an application kit may be obtained from the Office of Grants Inquiries, Division of Research Grants (DRG), NIH. The original and six copies of the application should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20892

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research grant applications, and in accord with the usual NIH peer review procedures. Applications will first be reviewed Federal scientific consultants (Study Section), and then by the National Advisory Council of the appropriate Institute(s). The review criteria customarily employed by the NIH for regular research grant applications will prevail.

The title of this announcement should be typed under item 2 on page 1 of the application, and the word "yes" should be checked to indicate a response to this announcement.

The initial application receipt date is November 1, 1985. Subsequent receipt dates will be February 1, June 1, and October 1.

All PHS and NIH grant policies governing regular research project grants, including cost sharing, apply to applications received in response to this program announcement.

For further information contact:

Dr. Matti Al-Aish
Deputy Chief
Diagnostic Imaging Research Branch
Radiation Research Program
National Cancer Institute
National Institutes of Health
Landow Building - Room 8C-09
Bethesda, Maryland 20892

Telephone: (301) 496-9531

ANNOUNCEMENT

STUDIES OF DOSE FRACTIONATION AND VOLUME LATE EFFECTS IN NORMAL TISSUES USING ANIMAL MODELS

P.T. 34; K.W. 0715035, 0725015, 0785190

NATIONAL CANCER INSTITUTE

Initial Application Receipt Date: November 1, 1985

Subsequent Application Receipt Dates: February 1, June 1, October 1

The Radiation Research Program (RRP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI) through its Radiotherapy Development Branch (RDP) supports a broad spectrum of research into radiation biology, radiation physics and radiation therapy. The present program announcement is to encourage the submission of scientifically meritorious grant applications for studies of dose fractionation and volume late effects in normal tissues using animal models, especially as they relate to radiotherapy.

Over the years the doses used in radiotherapy have become increasingly fractionated. Overall treatment duration was protracted until acute responses, e.g., of skin and mucosae, no longer limited the total dose that could be delivered to a tumor. However, when protraction was sufficient to minimize acute reactions, the total dose became limited by the development of late complications, e.g., dermal contraction, necroses, bone fracture. The change in the type of dose limiting tissue reflects one difference in the fractionation response of early- and late-responding normal tissues. Whereas repair of sublethal damage occurs in both, regeneration of surviving target cells during the course of fractionated radiotherapy is less or absent in the late-responding tissues.

There is a considerable diversity in the dose fractionation patterns in use in major radiotherapy centers worldwide. Nevertheless, it seems unlikely that valid inter-institution comparisons of therapeutic ratios can be made from the literature.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title III, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

What is considered in the United States to be conventional or standard dose fractionation, consisting of regimens using 1.8-2 Gy/day, 5 days per week, is certainly not the most appropriate for all patients, and may not be the best for even the majority. Experimental evidence, both from the clinic and the laboratory, suggests that better results may be obtained for the same total dose by reducing the dose per fraction and shortening the overall time, and, therefore, the average interval between dose fractions. There is evidence to suggest that reducing the dose per fraction leads to an increase in the "tolerance" dose for lateresponding normal tissues which is greater than the increase in dose needed for a certain probability of tumor control. Shortening the overall treatment time reduces the extent of repopulation by tumor clonogens, although at the risk of compromising reoxygenation.

A second factor believed to modify the response of normal tissues is the volume of tissue irradiated. The volume effect is frequently discussed but rarely written about. It is a generally agreed-upon clinical impression that the phenomenon is important in dermal and spinal cord irradiation and is of course important in situations where the functional integrity of a complete organ is put at risk.

Although the severity of a normal tissue response increases with increase in the volume or area of tissue irradiated, it is not known if this applies to all tissues, nor whether it varies with fractionation pattern. The volume effect has rarely been well quantified and has not been investigated extensively in experimental animals.

The mechanism involved in the change in effect per unit of dose with change in volume is not understood. It is not known whether it is an increased induction of injury per unit of dose with increase in volume or a decreased ability of the host to recover from or compensate for an equal injury per unit of dose. It is important to understand the volume effect because of the clinical dilemma posed by the tolerance of normal tissues being modified to a significant, but poorly quantified, extent by the volume irradiated, while, in general, larger tumors require larger doses and larger treatment volumes for their control.

In the light of all these considerations RDB encourages investigator initiated grant applications:

- (1) to determine appropriate animal models for a variety of human tissues which are dose-limiting for curative radiotherapy;
- (2) to select endpoints and evaluation criteria and develop statistical considerations for dose fractionation and volume effects studies;
- (3) to determine the dose response relationships for late effects for fractionation schemes relevant to radiotherapy;
- (4) to determine whole and partial organ dose response relationships for late effects for fractionation schemes relevant to radiotherapy;
- (5) and to identify methods for predicting and/or measuring the onset and rate of regeneration in irradiated normal tissues as a function of various dose fractionation patterns.



This list is not meant to be exhaustive. Other applications consistent with the spirit of this announcement are welcome.

For further information contact:

Dr. Francis J. Mahoney
Radiotherapy Development Branch
Radiation Research Program
Division of Cancer Treatment
National Cancer Institute
National Institutes of Health
Landow Building - Room 8C08
Bethesda, Maryland 20892

Telephone (301) 496-9360

NIH Guide for Grants and Contracts

Vol. 14, No. 12, November 8, 1985

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

Change in Application Receipt Dates

Effective Date: January 1, 1986

P.T. 04, 22, 34, 44; K.W. 0710030, 0404000

The Division of Research Grants (DRG) NIH, receives applications for research and training grants and cooperative agreements for the Public Health Service (PHS). More than 30,000 competing applications are processed and assigned for review and funding each year.

Competing applications are received on a cycle linked to the meeting times of the initial review groups and the National Advisory Councils and Boards that review the applications. One of DRG's major responsibilities is to analyze application trends with a view toward making the best use of limited resources by distributing workloads as evenly as possible within the constraints of a cyclical review process. As a result of this analysis, DRG has established new receipt dates. These dates appear on the following page.

Please note these dates are effective January 1, 1986.

APPLICATION RECEIPT DATES, REVIEW AND AWARD SCHEDULE

Application Receipt Dates				Initial Review Group Dates	National Advisory Council/ Board Dates	Earliest Possible Beginning Date *
Jan. 10 May 10 Sept. 10 for	Feb. 1 June 1 Oct. 1 for	Mar. 1 July 1 Nov. 1 for	Apr. 15 Aug. 15 Dec. 15 for	May/June Oct./Nov. Feb./Mar.	Sept./Oct. Jan./Feb. May/June	Dec. 1 Apr. 1 July 1
All individual NRSA applications.* All new and competing continuation Institutional NRSA Training grant applications.	All new research grant applications, unless specified differently in a Program Announcement or Request for Applications. Career Development awards and Conference grant applications. New and competing continuation Program Project and Center applications.	Competing continuation & supplemental research grant applications.	Small Business Innovation (SBIR) Program, both Phases. (Phase II applicants must have completed a federally-funded Phase I project.)			

* Individual NRSA applications are not reviewed by Council. Their start dates are therefore approximately 4 months earlier than indicated.

* Individual NRSA applications are not reviewed by Council. Their start dates are therefore approximately 4 months earlier than indicated.

All applications must be received by the above dates. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday. The receipt date will be waived only in extenuating circumstances. To request such a waiver, include an explanatory letter with the signed completed application. No waiver will be granted prior to receipt of the application. It is in an applicant's best interest to submit early and avoid the otherwise unavoidable rush associated with announced receipt dates.

NOTICE

9TH ANNUAL NIH RESEARCH SAFETY SYMPOSIUM

P.T. 42; K.W. 0725015, 0715175

Radiation Safety Issues in Laboratory and Clinical Research Institutions

What the Non-Expert Needs To Know

December 16-17, 1985
Washington, D.C.

The Division of Safety, National Institutes of Health (NIH) is pleased to announce the 9th Annual NIH Research Safety Symposium. The symposium this year will focus on radiation safety issues in laboratory and clinical research institutions and, in particular, **what the non-expert needs to know about radiation safety.** Thus, the symposium should be of special interest to research institution administrators, managers, research support personnel, nursing and other patient-care staff, safety personnel, and their technical staffs.

Rather than a highly technical discussion, the symposium is designed to provide a forum for presenting and discussing those radiation safety issues which are important to an institution and to a broad spectrum of an institution's employees. The introductory session will provide an understanding of the uses and benefits of ionizing radiation in biomedical research and an awareness of the key terms and concepts related to radiation and radiation safety.

Radiation safety issues to be addressed include the following:

- o The risk of radiation exposure, including perception of risk, and radiation benefits.
- o The regulatory environment inherent to the use of radiation.
- o Radiation liability and litigation.
- o Strategies for reducing radiation risk.
- o Special concerns related to radiation and pregnancy.
- o Disposal of low-level radioactive waste in 1986.
- o Management of multi-hazard (biological, chemical, and radiological) situations.

Symposium Location:

Sheraton Washington Hotel
Connecticut Avenue at Woodley Road
Washington, D.C. 20009

Telephone: (202) 328-2000

The hotel is located on the Red Line of the Metro
Subway, Woodley Park-Zoo stop.

Accommodations:

A block of rooms has been reserved at the Sheraton Washington for symposium participants. The room rate is \$55.00 for a single and \$75.00 for a double. In order to be assured of a sleeping room, participants should contact the Sheraton Woodley Park Hotel by November 15, 1985.

Registration:

To register for the symposium, please return the registration form found on the last page of this issue no later than November 25, 1985 to:

Mark S. Brown
9th Annual NIH Research Safety Symposium
Social and Scientific Systems, Inc.
7101 Wisconsin Avenue, Suite 610
Bethesda, Maryland 20814

Telephone: (301) 986-4870

REGISTRATION FORM

9th Annual NIH Research Safety Symposium

Radiation Safety Issues in Laboratory and Clinical Research Institutions

What the Non-Expert Needs to Know

December 16-17, 1985
Washington, D.C.

Name: _____

Title: _____

Affiliation: _____

Address: _____

Please return this form by **November 25, 1985** to:

Mark S. Brown
9th Annual NIH Research Safety Symposium
Social and Scientific Systems, Inc.
7101 Wisconsin Avenue, Suite 610
Bethesda, Maryland 20814

Telephone: (301) 986-4870

NOTICECLINICAL TRIALS IN VISION RESEARCH

P.T. 34; K.W. 1002046, 0755015

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) is announcing its intention to support future clinical trials generally utilizing the COOPERATIVE AGREEMENT mechanism when an assistance mechanism of research support is deemed appropriate.

NEI clinical trials are research projects directed at improved prevention, diagnosis, prophylaxis, or treatment of human eye conditions. The goal of an NEI clinical trial is to identify risk factors for visual loss and to determine the safety and effectiveness of prophylactic, diagnostic, or treatment procedures in reducing visual loss.

Assistance mechanisms are used in general when the results or outcomes are primarily for the benefit of the scientific or clinical communities. The NEI employs two types of assistance mechanisms: cooperative agreements and research project grants. Cooperative agreements are used to support research when NEI staff are substantially involved in the conduct of the research. Applications for clinical trials may be submitted at the initiative of investigators, or in response to specific NEI Requests for Applications. In either case, potential applicants are strongly encouraged to communicate with NEI staff with respect to the preparation and submission of an application.

The rules and regulations affecting cooperative agreements are the same as those for regular grants. The only difference is that NEI staff are to be involved in the conduct of the trial along with the investigators according to specific terms and conditions which are described in the Request for Applications (RFA) and included in the Notice of Grant Award. In the case of investigator-initiated cooperative agreements, terms and conditions will be similar to those currently in use for institute-initiated clinical trials, but the applicant investigator or NEI staff may propose modifications appropriate to the particular study.

Copies of the Terms of Agreement which specify the areas of NEI staff involvement in current cooperative agreements are available on request. The terms and conditions are not likely to vary significantly from one trial to another, but are adapted for a particular study. Applicants who are considering initiating an application for an NEI-funded clinical trial should consult with the NEI.

This program is described in the Catalog of Federal Domestic Assistance No. 13.871, Sensory-Motor Disorders and Rehabilitation. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

In some instances it may not be practical for NEI staff to participate substantially in the conduct of some trials, for example, a single center trial of very limited scope, or a single center trial at a foreign institution; therefore, the support mechanism in these situations would be the regular research project grant. It is also likely that the National Eye Institute will continue to initiate a few clinical trials that are more directly a continuation of Institute research with the results intended for a direct Institute benefit; in these cases a contract mechanism will be utilized, as appropriate.

For further information or copies of current Terms of Award, please contact:

Dr. Israel Goldberg
Deputy Associate Director
Extramural and Collaborative Programs
National Eye Institute
Building 31 - Room 6A51
9000 Wisconsin Avenue
Bethesda, Maryland 20892

Telephone: 301 - 496-5983

NOTICEAVAILABILITY OF FROZEN SERUM PANELS

P.T. 36; K.W. 0780005, 0715035

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) is interested in evaluating serum assays which are potentially useful in cancer diagnosis, prognosis and the monitoring of therapy. Coded panels of frozen sera are available from two banks established by the Diagnosis Program, Division of Cancer Biology and Diagnosis. Sera are carefully collected and maintained in 1 ml glass vials at -70 C.

The Breast Cancer Serum Bank collection contains sera from breast cancer patients, benign disease patients and normal controls.

The Diagnosis Serum Bank collection contains sera from patients with a wide variety of neoplasms, patients with benign diseases and control subjects.

Requestors of test panels must document the discriminatory power of their assays by providing preliminary data, including: a brief description of the assay, results for cancer patients, results for patients with non-malignant disease and results for healthy normal control subjects. Reprints of pertinent publications or pre-publications should be included, when possible. The assays must provide accurate determinations with no more than 1 ml of serum. Requestors must agree to accept specimens under a blind code number and to report the results of their analysis to the NCI. Requestors will receive the panel code once their results have been verified by the NCI. Requests for coded serum panels should be sent to:

Project Officer
Breast Cancer Serum Bank

or

Project Officer
Diagnosis Serum Bank

Diagnosis Program
National Cancer Institute
National Institutes of Health
Westwood Building - Room 10A10
Bethesda, Maryland 20892

REVISED ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-OD-02

ACADEMIC RESEARCH ENHANCEMENT AWARD

P.T. 34, 14; K.W. 0710030

NATIONAL INSTITUTES OF HEALTH

Application Receipt Date: January 15, 1986

In its report accompanying the Fiscal Year 1985, appropriation for the National Institutes of Health (NIH) Congress called for an initiative to strengthen the research milieu of non-research-intensive, four-year colleges and universities that provide undergraduate training for a significant number of our nation's research scientists. In FY 85, the NIH made \$5,000,000 available for this purpose and will be able to award over 75 "Academic Research Enhancement Awards" (AREAs). This award is designed to enhance the research environment of educational institutions that have not been traditional recipients of NIH research funds. The award is intended to support new research projects or expand ongoing research activities proposed by faculty members of these institutions in areas related to the health sciences.

The NIH is inviting grant applications for a second round of AREAs to be awarded in FY 86.

Institutions eligible for the AREA Program are defined as those that offer baccalaureate degrees in the sciences related to health, but did not receive an NIH Biomedical Research Support Grant (BRSR) in four out of the five fiscal years from FY 1981 through FY 1985. If in doubt about whether an institution is eligible consult your institution's Office of Sponsored Research. Alternatively, contact either of the following offices at NIH:

Office of the Associate Director
for Extramural Affairs
Shannon Building - Room 111
National Institutes of Health
Bethesda, Maryland 20892

Telephone: (301) 496-5356

or

Office of Special Programs and Initiatives
Building 31 - Room 1B54
National Institutes of Health
Bethesda, Maryland 20892

Telephone: (301) 496-1968

Investigators eligible for the Program are those who will not have active research grant support (including an AREA) from either NIH or ADAMHA (Alcohol, Drug Abuse, and Mental Health Administration) at the time of award of an AREA grant. Applicants for AREAs may not submit a regular NIH or ADAMHA research grant application for essentially the same project.

Funding decisions will be based on the proposed research project's scientific merit and relevance to NIH programs, and the institution's contribution to the undergraduate preparation of doctoral-level health professionals. Among projects of essentially equivalent scientific merit and program relevance, preference will be given to those submitted by institutions that have granted baccalaureate degrees to 25 or more individuals who, during the period 1977-1984, obtained academic or professional doctoral degrees in the health related sciences.

AREAs are awarded on a competitive basis. Applicants may request support for up to \$50,000 in direct costs (plus applicable indirect costs) for a period not to exceed 24 months. Although this award is non-renewable, it will enable qualified individual scientists within the eligible institutions to receive support for feasibility studies, pilot studies and other small-scale research projects preparatory to seeking more substantial funding from the regular NIH research grant programs.

Applications for this award will be accepted under the regular application submission procedures of the Division of Research Grants (DRG) of NIH. Grant applications must be prepared and submitted on PHS 398 grant application forms. An abbreviated format and simplified instructions will be provided for use in preparing these applications. The receipt date is January 15, 1986.

Those individuals and institutions meeting eligibility requirements and wishing to receive further information and/or application materials should write to:

AREA
Office of Grant Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
Bethesda, Maryland 20892

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-AM-02

ADDITIONAL CLINICAL CENTERS FOR THE DIABETES CONTROL AND
COMPLICATIONS TRIAL (DCCT)

P.T. 34, 04; K.W. 0715075, 0755015

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY
DISEASES

Application receipt date: January 21, 1986

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) announces the availability of a Request for Applications (RFA) inviting applications for additional Clinical Centers to participate with the NIADDK in the ongoing Diabetes Control and Complications Trial (DCCT). The DCCT is a multicenter collaborative clinical trial to assess the relationship between metabolic control and development of the early vascular complications of insulin-dependent diabetes mellitus (IDDM). The DCCT was designed to consist of four sequential phases:

Phase	I	--	Planning
Phase	II	--	Feasibility Study
Phase	III	--	Full-Scale Trial
Phase	IV	--	Data Analysis and Reporting

The Protocol for the DCCT was developed during Phase I and tested during Phase II. Based on the results from this feasibility study, the NIADDK has determined that it will proceed with the full-scale clinical trial which is expected to run until June 1993. Four to six additional Clinical Centers will be selected to join with the existing 21 DCCT Clinical Centers (listed below) in the conduct of the full-scale clinical trial (Phase III) and the data analysis and reporting phase (Phase IV).

The main rationale for adding new Clinical Centers at this juncture in the DCCT is to assure that a sufficient sample size of volunteers can be recruited and followed to provide adequate statistical power to answer the major study question. Selection of additional Clinical Centers will also address the problem of poor geographic distribution of the current Clinical Centers; therefore, preference will be given to applicants from institutions in metropolitan areas of the contiguous 48 states of the United States currently unserved by a DCCT Clinical Center.

The assistance mechanism that will be used to support the additional Clinical Centers, the cooperative agreement, is similar in many respects to the traditional NIH research grant; however, it differs from a research grant principally in the extent and nature of the involvement of NIADDK staff. The staff of the NIADDK is substantially involved as an active partner in all aspects of the scientific and technical management of the DCCT above and beyond the levels required for administration of traditional research grants.

An RFA is available which outlines the DCCT in more detail, the requirements for participation as a Clinical Center, and the method of applying. The deadline for receipt of applications for Clinical Centers is January 21, 1986. Applications received after this date will not be considered. Additional information and copies of the RFA and the DCCT Protocol can be obtained from:

Carolyn Siebert, M.P.H.
Clinical Trial Coordinator
Diabetes, Endocrinology and Metabolic Diseases
National Institute of Arthritis, Diabetes, and
Digestive and Kidney Diseases, NIH
Westwood Building - Room 628
Bethesda, Maryland 20892

Telephone: (301) 496-7645

DCCT Clinical Centers

Case Western Reserve University, Cleveland	University of Minnesota, Minneapolis
Children's Hospital of Philadelphia	University of Missouri at Columbia
Cornell University, New York City	University of Pittsburgh
Henry Ford Hospital, Detroit	University of Tennessee, Memphis
Joslin Diabetes Center, Inc., Boston	University of Texas, Dallas
Massachusetts General Hospital, Boston	University of Toronto
Mayo Foundation, Rochester	University of Washington, Seattle
Medical University of South Carolina, Charleston	University of Western Ontario, London
Park Nicollet Med. Fdn., Minneapolis	Vanderbilt University, Nashville
University of Iowa, Iowa City	Washington University, St. Louis
	Yale University, New Haven

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-ES-01

NON-MAMMALIAN SPECIES IN TOXICOLOGICAL TESTING

P.T. 34; K.W. 1007001, 1007003, 1007009

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Application Receipt Date: February 15, 1986

I. BACKGROUND INFORMATION

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency in support of research and training related to understanding of the biological effects of substances found in the environment on human health. The Institute is seeking research applications to develop and compare non-mammalian methods of animal testing of biologically active environmental substances with traditional animal methods. Historically, the Institute has supported Marine and Freshwater Biomedical Centers which provide core support to facilitate multidisciplinary research on marine and freshwater organisms as model systems for elucidating mechanisms of toxicity of environmental agents. Other center and project grants supported by the NIEHS focus their research on the development of in vitro systems to supplement or reduce in vivo studies for the evaluation of chemicals of environmental concern. The Institute also pursues this objective through the contract mechanism.

II. GOALS AND SCOPE

The NIEHS requests research applications directed toward development, validation and use of non-mammalian methods of animal testing which can be employed to study the biological effects of environmental agents. The Institute will favor applications that aim to study the similarities and differences between biological effects in mammalian and non-mammalian species and how these findings might bear upon interpretation of possible effects in humans.

- A. It is expected that non-mammalian species may be employed for the following applications.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.112, Characterization of Environmental Health Hazards; 13.113, Biological Response to Environmental Health Hazards; 13.114, Applied Toxicological Research and Testing; 13.115, Biometry and Risk Estimation. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

1. Screening tests: The development, validation and testing of methods to screen xenobiotics for biologic effects.
2. Detection of exposure: Develop methods which will facilitate the early detection of exposure to xenobiotics and serve as sentinels of ecological damage.
3. Species substitution: Develop the use of non-mammalian species for toxicological testing to provide information of the quality and kind now obtained through the use of traditional animal modes.

III. METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application form for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division of Research Grants, NIH. The original and six copies of the application must be received by February 15, 1986. Applications must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20892

The face page of the application should be labeled **"In response to RFA 86-ES-01."**

IV. STAFF CONTACT

Questions relating to this announcement should be directed to:

Dr. Edward Gardner, Jr.
Program Director, RGP, EP
National Institute of Environmental
Health Sciences
P O. Box 12233
Research Triangle Park, NC 27709

Telephone: 919-541-7724

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS

86-NS-01

CLINICAL EVALUATION OF COPOLYMER I FOR EXACERBATING-REMITTING

MULTIPLE SCLEROSIS - A MULTI-INSTITUTIONAL CLINICAL TRIAL

P.T. 34; K.W. 0715140, 0755015

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Application Receipt Date: January 21, 1986

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) invites applications for a cooperative agreement to support a multi-institutional clinical trial of copolymer I for exacerbating-remitting multiple sclerosis (ER MS).

I. BACKGROUND

The prophylactic and therapeutic effects of the synthetic polypeptide copolymer I have been demonstrated in a variety of animals with experimental autoimmune encephalomyelitis. The safety of copolymer I in man has also been demonstrated in a small number of MS patients. In a recent small pilot study in patients with ER MS copolymer I was reported to reduce the number and frequency of relapses and to modify the degree of disability assessed at two years after initiation of therapy.

Although the etiology and pathogenesis of MS are unknown, the search for a therapeutic modality that will retard or arrest the ingravescent course of MS is pressing. Preliminary studies suggest that copolymer I may offer promise of such efficacy. The precise mechanism of action of copolymer I remains to be established, but the favorable results of pilot studies urge early and comprehensive evaluation of its efficacy and safety. The potential for defining and optimizing the putative beneficial effect of copolymer I only can be realized by a carefully designed multi-institutional collaborative clinical trial. The execution of such a trial requires a major commitment of time and resources by clinician scientists. Program planning is desirable in the effort to demonstrate the effect of copolymer I before it is introduced into general use.

This program is described in the Catalog of Federal Domestic Assistance No. 13.853. Awards will be made under the authority of Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

II. RESEARCH GOALS AND SCOPE

A collaborative, multi-institutional, randomized, placebo-controlled trial would be proposed for evaluating the effectiveness and safety of copolymer I in modifying the clinical course of exacerbating-remitting multiple sclerosis. The proposed trial should allow for the confident:

- A. Determination of the safety of copolymer I in humans in a large population of MS patients.
- B. Identification of the co-existing conditions that contraindicate the use of copolymer I.
- C. Confirmation and validation of the effect, or lack of effect, of copolymer I in reducing the frequency of attacks in ER MS patients.
- D. Determination of whether copolymer I significantly modifies the long-term disability of ER MS patients.

The NINCDS staff will participate with the awardee primarily through the Multiple Sclerosis Clinical Trial Monitoring Committee (MS-CTMC), in the conduct of the study, e.g., in the decisions to proceed from one step of the study to the next, such as refinement of the protocol and procedural manual, patient recruitment, treatment and follow-up, termination of recruitment, and data analysis. Staff will assist in the modification, if necessary, and implementation of criteria for excluding from the study those patients who may experience untoward reactions, and of interim data analyses for safety and efficacy. Full details of NINCDS's involvement are outlined under "Terms of the Award" in the complete RFA.

III. MECHANISM OF SUPPORT

The award will be made as a cooperative agreement. A cooperative agreement is an assistance instrument with substantive participation of NINCDS staff during performance of the project. The terms of NINCDS staff participation, which the awardee institution and principal investigator must accept, are included in the complete RFA.

The NINCDS anticipates making a single award as a result of this request. It is anticipated that \$1 million will be available to fund the initial year's award. The award will be made for a period of up to five years. The starting date for the initial annual period will be on or around July 1, 1986.

All policies and requirements that govern the grant programs of the U.S. Public Health Service apply, including the requirement for cost sharing. Although this program is provided for in the financial plans of the NINCDS, the award of a cooperative agreement pursuant to this RFA is also contingent upon the continuing availability of appropriated funds for this purpose.

IV. STAFF CONTACT

A copy of the complete RFA describing the research goals and scope, the nature of NINCDS staff participation, the review criteria and method of applying can be obtained by contacting:

Emanuel M. Stadlan, M.D.
Deputy Director
Demyelinating, Atrophic, and Dementing
Disorders Program
National Institute of Neurological
and Communicative Disorders and Stroke
Federal Building - Room 700
7550 Wisconsin Avenue
Bethesda, Maryland 20892

Telephone: (301) 496-2313

ANNOUNCEMENT

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANTS

P.T. 36; K.W. 0735015, 1002024, 1014001

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: February 15, 1986

I. BACKGROUND

The Division of Research Resources (DRR) is continuing its competitive Biomedical Research Support (BRS) Shared Instrumentation Grant Program initiated in Fiscal Year 1982. The program was established in recognition of the long-standing need in the biomedical research community to cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment. The objective of the program is to make available, to institutions with a high concentration of PHS-supported biomedical investigators, research instruments which can only be justified on a shared-use basis and for which meritorious research projects are described.

Eligible institutions may submit more than one application for different instrumentation in the Fiscal Year 1987 review cycle.

II. RESEARCH GOALS AND SCOPE

This program is designed to meet the special problem of acquisition and updating of expensive shared-use instruments which are not generally available through other PHS mechanisms, such as the regular research, program project and center grant programs, or the Biomedical Research Support (BRS) Grant Program. Proposals for the development of new instrumentation will not be considered.

III. ELIGIBILITY

The BRS Shared Instrumentation Grant Program is a subprogram of the BRS Grant Program of DRR. Awards are made under the authority of the BRS program and are made to institutions only, not to individuals. Therefore, eligibility is limited to institutions which receive a BRS grant award. Awards are contingent on the availability of funds.

This program is described in the Catalog of Federal Domestic Assistance No. 13.337, Biomedical Research Support. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

IV. MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants provide support for expensive state-of-the-art instruments utilized in both basic and clinical research. Applications are limited to instruments that cost at least \$100,000 per instrument or system. Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers and cell sorters. Support will not be provided for general purpose equipment or purely instructional equipment. Proposals for "stand alone" computer systems will only be considered if the instrument is solely dedicated to the research needs of a broad community of PHS-supported investigators. Awards will be made for the direct costs of acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the normal purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is \$300,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. Cost sharing is not required. If the amount of funds requested does not cover the total cost of the instrument, an award will not be made unless the remainder of the funding is assured. Description of the proposed co-funding must be presented with the application. Assurance of co-funding, signed by an appropriate institutional official, must be presented to DRR prior to the issuance of an award.

A major user group of three or more investigators should be identified. Each major user must have PHS peer-reviewed research support at the time of the award. The application must show a clear need for the instrumentation by projects supported by multiple PHS research awards and demonstrate that these projects will require at least 75% of the total usage of the instrument. Major users can be individual researchers, or a group of investigators within the same department or from several departments at the applicant institution. PHS extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument can be made available to other users upon the advice of the advisory committee. These users need not be PHS awardees but priority should be given to PHS supported scientists engaged in biomedical research.

A progress report will be required which describes the use of the instrument, listing all users, and indicating the value of the instrumentation to the research of the major users and to the institution as a whole.

V. ADMINISTRATIVE ARRANGEMENTS

Each applicant institution must propose a Principal Investigator who can assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility should also be utilized. The Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation of all reports required by the NIH, for relocation of the instrument within the

grantee institution if the major user group is significantly altered and for continued support for the maximum utilization and maintenance of the instrument in the post award period.

A plan should be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument should be described.

VI. REVIEW PROCEDURES AND CRITERIA

Applications are reviewed by specially convened initial review groups of the Division of Research Grants (DRG) for scientific and technical merit and by the National Advisory Research Resources Council of the DRR for program considerations. Funding decisions are the responsibility of the DRR and will not be made prior to November 15, 1986.

Criteria for review of applications include the following:

- A. The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.
- B. The availability and commitment of the appropriate technical expertise within the major user group or the institution for use of the instrumentation.
- C. The adequacy of the organizational plan and the internal advisory committee for administration of the grant including sharing arrangements for use of the instrument.
- D. The institution's commitment for continued support of the utilization and maintenance of the instrument.
- E. The benefit of the proposed instrument to the overall research community it will serve.

VII. METHOD OF APPLYING

Copies of a more detailed announcement are being mailed to Program Directors of BRS grants and to sponsored program offices at all institutions currently receiving BRS grants. Interested investigators should obtain the complete announcement prior to preparing an application.

Applications must be received by February 15, 1986. Applications received after this date will not be accepted for review in this competition. The original and four copies should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
5333 Westbard Avenue
Bethesda, Maryland 20892

Inquiries and two copies of the application should be submitted to:

Biomedical Research Support Program
Division of Research Resources
National Institutes of Health
Building 31 - Room 5B23
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 496-6743

ANNOUNCEMENT

DEMONSTRATION AND EDUCATION RESEARCH IN CYSTIC FIBROSIS

P.T. 34; K.W. 0715135, 0715165, 0403004, 0502017, 0414000

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: February 1, June 1 and October 1

Cystic fibrosis is the most frequent lethal genetic disease of white Americans, affecting about 30,000 people in the United States. Although in the past cystic fibrosis patients have died at a very early age, today the average age for survival is more than 20 years. The disease may affect several body organs, including the lungs, pancreas, intestines, liver, gallbladder, and reproductive system, but the pulmonary aspects are the most pervasive and life threatening.

Treatment of cystic fibrosis is a complicated process of dealing with the symptoms present in the several organ systems involved and necessitates patient and family cooperation to maintain a continuing treatment regimen. Patients must adhere to a medication schedule, exercise, eat an adequate diet with supplementary digestive enzymes, and perform postural drainage. Moreover, patients must adjust to a chronic disease which will be fatal at a relatively young age. Depression, anger, and family tension are frequently seen in cystic fibrosis, often hindering the medical management and self-management of the disease. Compliance with treatment may be sporadic. In adolescence, especially, compliance often decreases and the normal struggles for independence are exacerbated by the continuing dependence on parental and medical involvement and economic dependence on parents. Moreover, cystic fibrosis patients often do not have normal social relationships.

Given this complicated medical picture, education of CF patients and their families is essential. Cystic fibrosis centers around the country consider education an important part of the medical management, but education of CF patients has not yet emerged as an area of research.

The intent of this announcement is to emphasize the importance of the problem and to invite the cooperation of investigators to address and offer solutions to this multifaceted problem. It is expected that applications will be submitted by multidisciplinary teams that may include, but will not be limited to, pulmonary physicians, nurses, behavioral scientists, and educators.

This program is described in the Catalog of Federal Domestic Assistance number 13.838, Lung Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Applications may deal with newly and/or previously diagnosed CF patients and their families. Adolescent CF patients could be studied as a special group. Emphasis should be on programs designed to encourage adherence to treatment plans, to reduce hospitalization, and to promote psychosocial adjustment. Evaluation of behavior change should be a major component.

APPLICATION SUBMISSION AND REVIEW

Application receipt dates for new applications are the regular application receipt dates of February 1, June 1, and October 1. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application Form PHS 398, which is available at most institutional business offices or from the Division of Research Grants (DRG), NIH.

To identify responses to this announcement, check "yes" and write **"Demonstration and Education Research in Cystic Fibrosis"** under item 2 of page 1 of the application. The completed application should be mailed to the following:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20892

The DRG will assign applications for review according to the NIH process for regular research grant applications. Additional information may be obtained by contacting:

Joan M. Wolle, Ph.D., M.P.H.
Prevention, Education, and
Research Training Branch
Division of Lung Diseases
National Institutes of Health
Westwood Building - Room 640
5333 Westbard Avenue
Bethesda, Maryland 20892

Telephone: (301) 496-7668

ANNOUNCEMENT

SMALL GRANTS PROGRAM FOR EPIDEMIOLOGY

P.T. 34; K.W. 0715035, 0785055

DIVISION OF CANCER ETIOLOGY

NATIONAL CANCER INSTITUTE

Application Receipt Dates: February 1, June 1, October 1

The Division of Cancer Etiology, National Cancer Institute (NCI) invites Small Grant applications relating to cancer epidemiology beginning with the February 1 receipt date in 1986.

I. PURPOSE OF THE AWARD

This is a short-term award, not to exceed two years, intended to provide support for pilot projects, testing of new techniques, or innovative or high-risk projects which could provide a basis for more extended research.

II. ELIGIBLE APPLICANTS

Investigators are eligible to apply for a Small Grant to support research on a topic relevant to cancer etiology if they are interested in:

- A. Planning a complex epidemiologic investigation.
- B. Developing or validating a laboratory procedure for the ultimate purpose of applying it in cancer epidemiologic research.
- C. Carrying out an innovative epidemiologic research project not related to on-going supported research, for which rapid funding is justified (the availability of special personnel for limited time periods is considered to be an important factor in evaluating the need for rapid funding).

If the research will constitute a doctoral dissertation, a written statement from the applicant's dissertation chairperson or equivalent academic

This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241, 42 USC 282) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

supervisor that the project proposal has his/her approval must accompany the application; if the study is selected for support under this program, a statement of approval of the full dissertation committee is required before funding will be made.

III. TERMS OF THE AWARD

The award will provide a maximum of \$25,000 in direct costs. These funds may be used for technical assistance, supplies, small equipment, and travel required by the project. Salary support for the principal investigator will not be allowed. The normal duration of support is one year but applications may be made for longer periods (up to two years) if the limit on total funding noted above is not exceeded. The NCI expects to make approximately 8 awards from each review cycle. Unless specifically stated to the contrary herein, all policies and requirements which normally govern the grants programs of the PHS apply.

IV. REVIEW PROCEDURES AND CRITERIA

Applications will be reviewed for scientific and technical merit by a committee convened by NCI and consisting primarily of non-Federal scientists. All applications will be evaluated with respect to the following:

- A. The significance and scientific merit of the proposed project.
- B. The methodology, including information to be derived.
- C. The investigator's background and training for carrying out the project.
- D. Adequacy of the available and requested facilities.
- E. The adequacy of justification presented for budget requests.

In addition to these general criteria, the following specific ones will apply as appropriate:

1. For pilot projects, the appropriateness of the exploratory activities and the likelihood that their completion will provide the basis for a definitive protocol.
2. For high-risk, innovative research, the extent to which completion of the proposed activities is likely to yield insight into the need for additional research.
3. For dissertation research, the quality of the education environment and the supervision to be provided the candidate.

Applications not meeting one of the three criteria stated above under "Eligible Applicants", or failing to meet the page limitations specified in this announcement, will be returned to the proposed Principal Investigator without undergoing committee review.

V. METHOD OF APPLYING

Applications shall be submitted on Form PHS 398, available at most institutional business offices or from the Division of Research Grants, NIH. Because the guidelines for preparing this application are different from those used for regular research grants, the instructions given below must be followed in preparing and submitting an application.

An accelerated review is planned as follows:

<u>Receipt Date</u>	<u>Committee Review</u>	<u>Earliest Possible Review Funding Date</u>
October 1	November	January
February 1	March	May
June 1	July	September

In order to expedite the review of your application, you are asked to submit two sets of copies of the application. The copies you send to the Referral Office of the NCI are of great practical importance to you, because they can be sent to members of the review group with a minimum of delay. The two groups of copies are as follows:

Send or deliver the original (typewritten and signed) and FOUR signed exact photocopies in one package to the Division of Research Grants using the mailing label enclosed in the application kit, as specified in the general instructions. Clearly label the outside of the package: **PROGRAM ANNOUNCEMENT RESPONSE: SMALL GRANTS PROGRAM FOR EPIDEMIOLOGY, DCE, NCI.** Enclose in that package the self-addressed three-part postcard, form PHS-3830.

IN ADDITION, in a separate package, mail or deliver 2 additional exact photocopies of the signed application to:

Referral Officer
Grants Review Branch
National Cancer Institute
Westwood Building - Room 820
5333 Westbard Avenue
Bethesda, Maryland 20892

Telephone: (301) 496-3428

Prospective applicants are encouraged to contact:

Dr. Genrose Copley
Landow Building - Room 8C16
7910 Woodmont Avenue
Bethesda, Maryland 20892

Telephone: (301) 496-9601

VI. REPORTING REQUIREMENTS

If an award is made in response to a Small Grants Application, a Final Progress Report and an Invention Statement must be submitted within ninety days after the termination of the award. This final reporting requirement is the same as that for other types of research grants and is in accord with 45 CFR 74.82. The information will be especially helpful to the NCI in evaluating the usefulness of the Small Grant Award Mechanism.

VII. SUPPLEMENTARY INSTRUCTIONS FOR APPLICANT-INVESTIGATORS, SMALL GRANTS PROGRAM FOR EPIDEMIOLOGY

Applications are to be submitted on the standard PHS research grant application form (PHS-398, Rev. 5/80), following the instructions supplied with those forms EXCEPT for the following (see pages 8-15, Instruction Sheet for PHS-398):

- A. Face Page of Application Item 2: DCE Small Grants Program for Epidemiology. Item 6: Ordinarily, only one year of support is provided; within the limits on total funding, however, applicants may apply for up to two years of support. Item 10: Not applicable; mark NA.
- B. Application page 4: Detailed Budget for First 12-Month Period. Funds should be limited to the following categories: personnel (including technicians), supplies, travel and small equipment items. All requests for expenditures must be strongly and SPECIFICALLY justified. The total request may not exceed \$25,000 in direct costs. (Use a separate page for this explanation of the need for proposed expenditures.)
- C. Application page 5: Budget Estimates for All Years. Applicants requesting one year's support should not submit this. (In that case, this page may be used to justify budget requests for the one-year project period.)
- D. Biographic data: Do not exceed one page except in the case of dissertation research. It is expected that the doctoral candidate's dissertation adviser will be the P. I. and thereby signifies approval of the protocol. Additional documentation which permits evaluation of the educational environment and supervision to be provided this research should be included together with pertinent information about the candidate.
- E. Section 2 of application: (follows page describing Resources and Environment)
 1. Specific Aims: Not to exceed one page.
 2. Significance: Not to exceed one page.
 3. Progress Report/Preliminary Studies: If applicable, not to exceed two pages.
 4. Experimental Design and Methods: Not to exceed ten pages.
 5. Human Subjects through Literature Cited: Not to exceed four pages.

These page limitations and others in the PHS-398 Application Instructions must be observed or the application will not be accepted. If an exception to this requirement is necessary, discussion with Program staff and a brief written explanation is necessary prior to submission.

VIII. SUGGESTIONS FOR PERSONS PREPARING APPLICATIONS FOR THE DCE SMALL GRANTS PROGRAM

As applicant-investigator, you are responsible for preparing an application which conveys the maximum information to reviewers, in the clearest possible form, and with the minimum of verbiage.

The DCE Small Grants Program is intended to offer rapid review of applications requesting limited support of certain budget categories (technicians, supplies and equipment). Please note that all expenditures included in the budget plan require explicit and strong justification. Some suggestions follow, to help you in demonstrating how your project meets program goals.

- A. Be sure you specify which of the target groups of investigators you represent (planning an epidemiologic study, developing a test for future epidemiologic use, innovative or high-risk studies, dissertation research.)
- B. Make it clear why pilot data are needed, or how the proposed research is innovative.
- C. It is important that the specified page limitations for each section of the text be strictly observed. Note, for example, that the section describing methods may not exceed 10 pages. This abbreviated format means that you must present your case with special clarity.
- D. Be sure to list your most important positions and publications relevant to this project in your biographic data.

ANNOUNCEMENT

SMALL GRANTS PROGRAM FOR PILOT PROJECTS

P.T. 34; K.W. 0706000, 1002024, 1014001, 0790000, 1004000

BIOMEDICAL RESEARCH TECHNOLOGY PROGRAM

DIVISION OF RESEARCH RESOURCES

Application Receipt Dates: February 1, June 1, October 1

The Biomedical Research Technology Program was established in 1962 to provide biomedical research scientists with complex technological capabilities required to solve biomedical and clinical research problems. This is primarily done by funding regional resources for the application of advanced technologies to biomedical research problems and the development of new instrumental and methodological approaches to such problems. At present the Program focuses on knowledge engineering, information technology, digital technology, biomedical engineering, and technologies for the study of biomolecular and cellular structure and function. To further this mission, the BRT Program supports a small grant award for support of pilot studies. Approximately ten to twenty awards per year are made, contingent on receipt of meritorious applications and appropriated funds.

I. PURPOSE OF THE AWARD

This is a one-year, non-renewable award for pilot projects in a high technology in engineering, instrumentation, physics or computer science related to biomedical research. The projects should involve feasibility studies of innovative ideas in a high technology. High technology is defined here as working at the limits of understanding of a technology. The project should be oriented towards new instrumental or methodological approaches and provide a basis for more extended research in the project's technology.

This program is described in the Catalog of Federal Domestic Assistance No. 13.371, Biotechnology Research. Awards will be made under the authority of the Public Health Service Act, Title 111, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 42 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency reviews.

The purpose of the small grants program is to:

- A. Provide an opportunity to test new ideas in a high technology that will lead to a larger research project or implementation of the technology in a working environment such as a BRT resource.
- B. Develop significant changes in an existing high technology important to biomedical research.
- C. Translate scientific notions into a basis for a future technology.

II. ELIGIBLE APPLICANTS

This program is open to both non-profit and for profit organizations and is designed to support engineers and other scientists for work in high technological projects in the biomedical area. (The BRT Program has a New Investigator Research Award program for recently trained or less experienced scientists.)

III. APPLICATION AND REVIEW PROCEDURE

Applications should be submitted on Form PHS 398, available at most institutional business offices or from the Division of Research Grants, NIH. Because the format for preparing this application is different from that used for regular research grants, additional information and instructions should be obtained from the BRT Program staff contact listed below. Applications must adhere to this format to be responsive. Unresponsive applications will be returned to the applicant without review. An accelerated review will be scheduled as follows:

Receipt Date Annually	Institute Committee Review	Council Review	Earliest Date for Funding
February 1	March-April	May-June	June
June 1	July-September	Sept.-Oct.	November
October 1	November-January	Jan.-Feb.	February

Applications recommended for approval will either be funded or withdrawn immediately after review by the National Advisory Research Resources Council.

IV. REVIEW CRITERIA

Applications will be evaluated with respect to the following criteria: the significance and scientific merit of the proposed project; its characterization as an innovative pilot project in a high technology in engineering, instrumentation, physics or computer science related to biomedical research; the probability the study will provide a basis for more extended research in the projects technology; the methodology, including choice of experimental methods, equipment or materials; the investigator's background and training for carrying out the project; adequacy of the available and requested facilities; and the adequacy of justifications presented for budget requests.

In the review of these applications the following aspects of the work proposed in the applications are emphasized:

- o scientific merit,
- o innovative approach or drastically different approach, and
- o the risk or uncertain chance of success because no historical base exists.

The award may not be used to supplement support for an ongoing project.

V. FUNDING CRITERIA

Applications will compete with each other in accordance with the purposes of the small grant program.

VI. TERMS OF THE AWARD

The award will provide a maximum of \$25,000 (direct costs) for personnel, consultants, supplies, small equipment, and travel required by the project. The award will be for one year, and in most cases can be extended for an additional year without additional funds.

VII. STAFF CONTACT

For further information prospective applicants are strongly urged to contact:

Dr. Jack Hahn, Ph.D.
 Head, Computer Technology Section
 Biomedical Research Technology Program
 Division of Research Resources
 National Institutes of Health
 Building 31 - Room 5B 43
 9000 Rockville Pike
 Bethesda, Maryland 20892

Telephone: (301) 496-5411

ANNOUNCEMENT

OPPORTUNITIES FOR RESEARCH ON ADOLESCENT FAMILY LIFE

INVESTIGATOR-INITIATED RESEARCH GRANTS AND NEW INVESTIGATOR RESEARCH AWARDS

P.T. 34; K.W. 0775020, 0710005, 0404000, 0730005

OFFICE OF ADOLESCENT PREGNANCY PROGRAMS
OFFICE OF POPULATION AFFAIRS, PHS

Application Receipt Dates: February 1, June 1, and October 1

I. BACKGROUND

The Adolescent Family Life (AFL) Program was enacted in 1981, to develop and evaluate model demonstration projects to postpone adolescent sexual activity; develop and evaluate model demonstration care projects that provide comprehensive health and social services for pregnant or parenting teens; present adoption as a viable option to parenthood for young, unmarried mothers; and conduct research on related topics. The AFL research component has both basic and applied thrusts in order to provide knowledge needed to support the range of AFL program goals.

II. RESEARCH GOALS AND SCOPE

The following research problem areas have been identified as those most needing attention from the viewpoint of the AFL Program:

A. Influences on Adolescent Premarital Sexual Behavior:

Demographic, economic, social, psychological, and physical characteristics that are related to adolescent premarital sexual activity; the influence of family, peers, the media, and other factors on the initiation of adolescent premarital sexual activity; the adolescent's decision-making process about premarital sexual activity as this is influenced by developmental stage, societal attitudes, ethical values, family/peer relationships, and other factors that enter into the decision-making process. Different patterns of influence for adolescent males and females.

This program is described in the Catalog of Federal Domestic Assistance No. 13.111, Adolescent Family Life Research Grants. Awards are made under the authority of Title XX of the Public Health Service Act and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review, unless the proposed research would establish a demonstration project for purposes of collecting data.

B. Consequences of Adolescent Premarital Sexual Behavior:

The effects of adolescent premarital sexual behavior on adolescent males and females, particularly with regard to their development (psychological, social, educational, moral, etc.) and physical health; how these consequences differ for major subgroups of the population or other groupings.

C. Consequences of Adolescent Premarital Pregnancy:

Social, psychological, physiological and other consequences of an adolescent premarital pregnancy and the social mechanisms that operate to ameliorate the negative consequences of such a pregnancy; impact on family of origin/extended family of an adolescent premarital pregnancy, family response to various stages of the pregnancy, and how these vary by major population subgroups or other groups.

D. The Adoption Option for the Unmarried Adolescent Mother:

Social, psychological, legal and service dimensions of the pregnant adolescent's adoption decision-making process. Role of the counseling process, social attitudes toward single parenthood, family involvement, the putative father, and the pregnant teen's own characteristics and expectations in the adoption decision-making process.

The effect (social, economic, or psychological) of the adoption decision on the adolescent mother, the child and/or the adoption family. Short and long-term adjustments and use of post-adoption services by an adolescent mother who places a child for adoption.

The differences among and usage of various adoption and care arrangements (formal adoption, informal adoption, temporary foster care, closed adoption and open adoption arrangements) and the differential outcomes for the adolescent mother, the child and/or the adoption family.

E. Parenting by the Unmarried Adolescent Mother:

Factors influencing parenting behavior of the unmarried adolescent mother and consequences of different kinds of parenting behavior for her and her offspring; role of unmarried adolescent mother's family of origin/extended family in adolescent parenting experience, how this differs by major population subgroups or other groupings, and the effect of such differences on the unmarried mother and her offspring; role of the father of the child of the unmarried adolescent mother in the parenting process and the impact of how his role is played on the mother and her child.

F. Adolescent Pregnancy Services:

The scope and impact of public and private sector services and policies directed toward adolescent pregnancy prevention, care, and parenting.

Evaluations of discrete strategies or interventions designed to eliminate adolescent premarital sexual relations and to assist families in effectively communicating their values about sexual matters to their children.

Evaluations of discrete strategies or interventions that might enhance service delivery of care services (e.g., health care, educational and vocational services, family planning services) to pregnant and parenting adolescents and their families.

Applications should include a well-organized statement of the problem to be addressed the research design, the conceptual framework within which the design has been developed, the methodology to be employed, the evidence upon which the analysis will rely, and the manner in which the evidence will be analyzed.

III. MECHANISMS OF SUPPORT

The support mechanisms for this program will be the individual research project grant award and the New Investigator Research Award (NIRA). Direct costs should not exceed \$100,000 for each year of the project in the former case and \$37,500 in the latter case. Awards can be made for a maximum of three years in both cases, although the Office of Adolescent Pregnancy Programs (OAPP) is particularly interested in shorter-term projects as well as those making use of already existing data. Yearly continuation of a multi-year award is contingent on grantee performance and availability of funds. Competition is open to any corporation, public or private institution or agency, including corporations operated for profit.

In order to make data available to others, copies of data sets and accompanying documentation produced with funds granted through this announcement will be deposited with a public use data archive or with OAPP. The cost of making such data available should be budgeted in the proposal.

This announcement is a standing announcement of opportunities for research on Adolescent Family Life and will prevail until superseded by a subsequent announcement. Funding decisions can be expected within eight months of an application receipt date.

Approximately one million dollars is available annually from OAPP for new awards in the AFL research area, contingent upon the receipt of appropriated funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

Applications in response to this solicitation will be reviewed on a nationwide basis and in competition with other submitted applications by committees convened by the Division of Research Grants (DRG) NIH, in accord with the usual NIH peer review procedures. Peer review criteria include:

- A. Scientific merit and significance of the project.
- B. Competency of proposed staff in relation to the type of research involved.
- C. Feasibility of the project.
- D. Reasonableness of proposed budget period in relation to the proposed research.
- E. Amount of grant funds necessary for completion, and adequacy of applicant's resources available for project.

- F. Adequacy of methodology proposed to carry out research.
- G. Adequacy of the proposed means for protecting against adverse effects upon humans, animals, or the environment, where an application involves activities which could have such effects.

Applications recommended for approval will be selected for funding by the Deputy Assistant Secretary for Population Affairs, Office of Population Affairs, on the basis of priority score, AFL program relevance, and availability of funds.

V. METHOD OF APPLYING

Applications should be prepared on PHS form 398, which is available in the business or grants and contracts office at most academic and research institutions or from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20892

Telephone: 301 - 496-7441

Completed applications should be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20892

Type across the mailing envelope and item two on the application face page: **"Research on Adolescent Family Life."** In addition, **"New Investigator Research Award"** should be added for proposals falling in this specialized category. Organizations which contemplate submitting a NIRA application should request the pamphlet, "New Investigator Research Awards," from DRG/NIH before developing the application and follow the guidelines contained therein.

VI. IDENTIFICATION OF CONTACT POINTS

Staff at the OAPP will assist to the extent possible in matters of scope, relevance, or other questions about review, administration, and funding of applications received in response to this announcement. Investigators are encouraged to contact the following individual:

Eugenia Eckard
Office Population Affairs, OASH, DHHS
Hubert H. Humphrey Building - Room 731E
200 Independence Avenue, S.W.
Washington, D.C. 20201

Telephone: 202 - 245-1181

ANNOUNCEMENT

OPPORTUNITIES FOR RESEARCH IN FAMILY PLANNING SERVICE DELIVERY IMPROVEMENT

INVESTIGATOR-INITIATED RESEARCH GRANTS AND NEW INVESTIGATOR RESEARCH AWARDS

P.T. 34; K.W. 0730010, 0730050, 0413002

OFFICE OF FAMILY PLANNING, OFFICE OF POPULATION AFFAIRS

PUBLIC HEALTH SERVICE

Application Receipt Dates: February 1, June 1, and October 1

I. BACKGROUND INFORMATION

The Office of Family Planning (OFP) which administers Title X of the Public Health Service Act, the major source of Federal funding for voluntary family planning services in this country, has an applied research program oriented toward the provision of knowledge that will enable the Title X program to improve its delivery of family planning services to low-income women and other clients in need of such services but otherwise unable to afford them. The knowledge sought is that needed by family planning service providers, particularly those at the clinic level, to better understand the service delivery processes with which they are involved and ways to influence these processes in the desired direction. Investigations of a number of topics can help build the needed knowledge.

II. RESEARCH GOALS AND SCOPE

The following research problem areas have been identified as those most needing attention from the viewpoint of family planning services delivery improvement:

- A. Family Planning Client Behavior: Factors influencing who comes to family planning clinics, when they come, their expectations, their satisfaction, effectiveness of their contraceptive behavior, and their pattern of clinic attendance and contraceptive use.

This program is described in the Catalog of Federal Domestic Assistance No. 13.974, Family Planning--Services Delivery Improvement Research Grants (SDI). Awards are made under the authority of Section 1004(a) of Title X of the Public Health Service Act (42 U.S.C. 300a-2(a) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review, unless the proposed research would establish a demonstration project for purposes of collecting data.

- B. Adolescent Family Planning Clients: Analyses of ways to better serve adolescents who are obtaining Title X services.
- C. Male Family Planning Clients: Identification of barriers to and strategies for bringing about effective involvement of males in family planning services; analyses of developmental processes that operate against responsible male sexual and family planning behavior.
- D. Targeting of Family Planning Services: Effectiveness of different kinds of strategies for targeting family planning services to low-income and other special needs clients (e.g., cultural or ethnic minorities, populations in rural or other distinctive geographical settings, unemployed, physically handicapped, mentally ill, or retarded); effectiveness of special approaches to delivery of family planning services for these subgroups.
- E. Clinic Personnel Behavior: Factors influencing the manner in which different types of family planning personnel perform their roles; consequences of such differences for effectiveness of clients' family planning behavior; successfulness of training or other strategies in enhancing personnel role performance; factors in recruiting and retaining competent family planning personnel; impact of clinic personnel characteristics on clinic quality of care and efficiency.
- F. Organization and Management of Family Planning Services: Effects of managerial and organizational factors at the clinic and other levels (e.g., funding arrangements, organization type, staffing patterns, facility/location characteristics) on efficiency and effectiveness of family planning service provision. Analyses of how costs can be contained or reduced while maintaining quality of family planning services provided; evaluations of how integration of family planning services with other services affects the character of family planning service provision.
- G. Role of Private Physician: Factors influencing role of private physician in providing family planning services to low-income women and adolescents.
- H. Natural Family Planning: Factors affecting choice of Natural Family Planning (NFP) as a method of fertility regulation in family planning clinics and other settings; determinants of NFP use-effectiveness; conditions under which NFP is an effective component of infertility services; studies of how to improve provision of NFP in family planning clinic settings.
- I. Infertility Services: Factors influencing the need for and provision of infertility services among low-income women; conditions for successful treatment of low-income women's various infertility problems; studies of how to improve provision of infertility services in Title X programs.
- J. Counseling Services: Evaluations of the role and effectiveness of various kinds of contraceptive education counseling approaches in different kinds of family planning clinic settings; studies of ways to include/improve counseling of pregnant adolescents concerning the adoption option in family planning clinic settings.

Applications should include a well-organized statement of the problem to be addressed, the research design, the conceptual framework within which the design has been developed, the methodology to be employed, the evidence upon which the analysis will rely, and the manner in which the evidence will be analyzed. The question of how findings from the proposed study will have general applicability to concerns of family planning services programs in this country should be addressed.

III. MECHANISMS OF SUPPORT

The support mechanisms for this program will be the individual research project grant award and the New Investigator Research Award (NIRA). Direct costs should not exceed \$100,000 for each year of the project in the former case and \$37,500 in the latter case. Awards can be made for a maximum of three years in both cases, although OFP is particularly interested in shorter-term projects as well as those making use of already existing data. Yearly continuation of multi-year awards is contingent on grantee performance and availability of funds. Competition is open to any public or private non-profit institution or agency.

In order to make data available to others, copies of data sets and accompanying documentation produced with funds granted through this announcement will be deposited with a public use data archive or with OFP. The cost of making such data available should be budgeted in the proposal.

This announcement is a standing announcement of opportunities for research in family planning service delivery improvement and will prevail until superseded by a subsequent announcement. Funding decisions can be expected within eight months of an application receipt date. Approximately one million dollars is available annually from OFP for new awards in the family planning service delivery improvement research area, contingent upon the receipt of appropriated funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

Applications in response to this solicitation will be reviewed on a nationwide basis and in competition with other submitted applications, by committees convened by the Division of Research Grants (DRG) NIH in accord with the usual NIH peer review procedures. Peer review criteria include:

- A. Scientific merit and significance of the project.
- B. Competency of proposed staff in relation to the type of research involved.
- C. Feasibility of the project.
- D. Reasonableness of proposed budget period in relation to the proposed research.
- E. Amount of grant funds necessary for completion, and adequacy of applicant's resources available for project.
- F. Adequacy of methodology proposed to carry out research.

- G. Adequacy of the proposed means for protecting against adverse effects upon humans, animals, or the environment, where an application involves activities which could have such effects.

Applications recommended for approval will be selected for funding by the Deputy Assistant Secretary for Population Affairs, Office of Population Affairs, on the basis of priority score, OFP program relevance, and availability of funds.

V. METHOD OF APPLYING

Applications should be prepared on PHS form 398, which is available in the business or grants and contracts office at most academic and research institutions or from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20892

Telephone: (301) 496-7441

Completed applications should be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20892

Type across the mailing envelope and item two on the application face page: **"Research in Family Planning Service Delivery Improvement."** In addition, "New Investigator Research Award" should be added for proposals falling in this specialized category. Organizations which contemplate submitting a NIRA application should request the pamphlet, "New Investigator Research Awards," from DRG/NIH before developing the application and follow the guidelines contained therein.

VI. IDENTIFICATION OF CONTACT POINTS

Staff at OFP will assist to the extent possible in matters of scope, relevance, or other questions about review, administration, and funding of applications received in response to this announcement. Investigators are encouraged to contact the following individual for further information:

Patricia Thompson, Ph.D.
Office of Family Planning
Office of Population Affairs
Hubert H. Humphrey Building - Room 731E
200 Independence Avenue, S.W.
Washington, D.C. 20201

Telephone: (202) 245-1181

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NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 14, No. 13, December 6, 1985

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

Change in Receipt Date - Requests for Applications

NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

85-CA-20 - Basic Studies on the Development and Assessment of Retroviral Vaccines

P.T. 34; K.W. 0740075, 10020445, 0710070, 0760080, 0715125, 0755020

85-CA-21 -Studies on Novel Human Exogenous and Endogenous Retroviruses

P.T. 34; K.W. 1002045, 0755035, 0780020, 0755045, 1002008, 0760015,
0760020

As noted in the flyer enclosed with the September 13, 1985 issue, a printing delay resulted in extremely late mailing of the NIH Guide for Grants and Contracts, Vol. 14, No. 10. Because the delay was even greater than originally believed, the National Cancer Institute and the National Institute of Allergy and Infectious Diseases are extending the receipt date for the two RFAs identified above. The new date is January 10, 1986.

NOTICE

NIH/FDA REGIONAL WORKSHOP - PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in biomedical and behavioral research. This particular workshop will be an intensive one-day workshop on IRB functions and responsibilities. The workshop will focus on selected case studies, illustrating representative problems of interpreting and applying the human subjects regulations. Participants will serve as IRB members in "mock IRB" meetings and compare strategies and solutions to issues raised by the cases. Enrollment will be restricted to 35-40 participants. Written materials will be supplied in advance to participants.

Date	Location	Contact
March 11, 1985	Little Rock, AR	Ms. Kathleen Masterson University of Arkansas Med. Center 4301 W. Markham Mail Slot 636 Little Rock, AR 77205 (501) 661-5502

A final list of dates and locations will be published at a later date. For specific program and registration information, contact:

Roberta H. Garfinkle
Office for Protection from Research Risks
National Institutes of Health
Building 31 - Room 4B09
9000 Rockville Pike
Bethesda, Maryland 20892

NOTICE

NATIONAL INSTITUTES OF HEALTH REGIONAL WORKSHOPS ON THE HUMANE CARE AND USE OF LABORATORY ANIMALS BY AWARDEE INSTITUTIONS

P.T. 42; K.W. 0201011, 1014003

The National Institutes of Health (NIH), Office for Protection from Research Risks (OPRR) is continuing to sponsor a series of workshops on implementing the revised "Public Health Service Policy on the Humane Care and Use of Laboratory Animals by Awardee Institutions" and the NIH Guide for the Care and Use of Laboratory Animals. The workshops are open to institutional administrators, animal care committee members, laboratory animal veterinarians, investigators, and others who share in responsibility for sound management of humane animal research. The current schedule includes:

<u>Date</u>	<u>Location</u>	<u>Contact</u>
March 12, 1986	Little Rock, AR	Ms. Kathleen Masterson Univ. of Arkansas Med. Ctr. 4301 W. Markham Mail Slot 636 Little Rock, AR 77205 (501) 661-5502
April 4, 1986	Boston, MA	Mrs. Virginia B. Werwath Harvard Medical Sch., NERPRC One Pine Hill Drive Southborough, MA 01772 (617) 481-0400 Ext 202

Additional workshops will be announced later. For further information regarding education programs contact:

Roberta H. Garfinkle
Education Program Coordinator
Office for Protection from Research Risks
National Institutes of Health
Building 31 - Room 4B09
9000 Rockville Pike
Bethesda, Maryland 20892

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

FDA-OP-86-1

CLINICAL STUDIES OF SAFETY AND EFFECTIVENESS OF ORPHAN PRODUCTS

P.T. 34; K.W. 0710100, 0755015

FOOD AND DRUG ADMINISTRATION

Application Receipt Date: January 21, 1986
(or 60 days after date of publication in Federal Register,
whichever is later)
(Please contact program office for date)

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of funds for Fiscal Year 1986 for awarding grants to support clinical trials on safety and effectiveness of orphan products. FDA has funds to award approximately 20 to 30 grants ranging from \$20,000 to \$70,000. The agency will consider grants greater than \$70,000 if they extend over a 2- or 3-year period.

I. BACKGROUND

FDA has established an Office for Orphan Products Development to identify and facilitate the availability of orphan products. Orphan products are drugs, biologics, medical devices (including in vitro diagnostics), foods for medical purposes, and veterinary products that may be useful in an uncommon or common disease but lack committed commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products for which there is evidence suggesting usefulness in an uncommon, serious disease but which are not labeled for that disease because substantial evidence is lacking. One way to make orphan products more easily available is to support research to determine whether the products are safe and effective. FDA has allocated funds to support such research.

II. RESEARCH GOALS AND OBJECTIVES

- A. **Clinical Studies:** FDA will consider only clinical studies for determining whether the products are safe and effective for premarket approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including the addition of new uses to marketed drugs. Ordinarily, there should already be available at least some preliminary clinical research suggesting effectiveness and relative safety. FDA will also consider applications where persuasive pharmacologic evidence is available that a product has a reasonable possibility of being effective even though no clinical trials have yet been performed. All studies subject to requirements for clinical investigations under the Federal Food, Drug, and Cosmetic Act are to be conducted in accordance with those requirements in addition to the requirements of the request for application (RFA).

Because funds are relatively limited, FDA cannot consider large research projects involving many subjects (human, or animal in the case of a veterinary drug) and long-term followup. The typical study considered for support may involve up to several dozen subjects, will be well-controlled and directed to providing substantial evidence of the product's safety and effectiveness. Pharmacokinetic studies will also be considered if they are necessary to determine safe and effective doses in subjects with serious organ disease that might affect drug disposition. FDA will consider pharmacokinetic studies, however, only if they are part of studies for determining effectiveness of a drug or are proposed as desirable information to obtain for drugs that already have a significant amount of evidence showing effectiveness. In designing a well-controlled study, the investigator should keep in mind that historical controls or use of the subject as his or her own control is generally less desirable and reliable than active control or, when ethical, placebo controls. In the case of veterinary products, research studies should be directed to the following area only: an orphan drug would be one for the prevention or mitigation of a serious zoonotic disease in humans by its prophylactic or therapeutic use in animals.

Each investigator submitting a grant application for a proposed human or veterinary orphan use in response to this RFA must include a short statement explaining why the proposed product meets the objectives of the orphan products development program as described above. This statement should be in the application under Section 2--"Significance."

- B. **Statistical Support:** Statistical expertise is helpful in the planning, design, execution, and analysis of clinical investigations and clinical pharmacology to ensure the validity of estimates of safety and efficacy obtained from human studies. Applicants will be expected to provide a statistical basis for the number of patients chosen for the trial based upon the proposed outcome measures. Applicants should also document the appropriateness of the statistical procedures to be used in analysis of the results.
- C. **Journal References:** Published reports are necessary and often times critical for the review process and can help to support the investigator's research intent. Applicants will be expected to include copies of reprints of the references necessary and critical for the review.

III. SUBMISSION REQUIREMENTS

(Please submit original set and six copies.)

1. Completed Form PHS 398, "Application for Public Health Service Grant." Please include a brief statement (rationale) of why the proposed product meets the objectives of the orphan products grants program. This statement should be part of "Significance" section of Section 2 - Research Plan.
2. Copies of all reprints critical to the review process should accompany the original and each copy of the grant application.
3. Completed Form HHS 596, "Protection of Human Subjects," Assurance/Certification/Declaration (Part of Form PHS 398).

4. Human Subject Consent Forms and/or Assent Form(s). If a study involves both adults and children, separate consent forms should be provided for the adults and the parents or guardians of the children. See 45 CFR 46.116 or 21 CFR 50.25 for elements of informed consent.

Important Note: Application forms are available from contract and grants business offices at most academic and research institutions. The above requirements are to be mailed to the FDA. Do not use the NIH mailing label at end of application kit.

IV. LETTER OF INTENT

Prospective applicants are requested to submit a brief letter of intent to submit an application which should include a brief synopsis of the research plan. The letter is to be submitted to Benjamin P. Lewis (address below).

V. STAFF CONTACT

The original and six copies of the completed application should be mailed to the following address:

Kathryn McKnight
State Contracts and Assistance Agreements
Branch (HFA-520)
Food and Drug Administration - Room 15A-17
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-6170

Copies of the complete RFA and additional information may be obtained from:

Benjamin P. Lewis
Health Scientist Administrator
Office of Orphan Products Development (HF-35)
Food and Drug Administration - Room 12A40
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4903

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-CA-02

CANCER CONTROL SMALL GRANTS RESEARCH PROGRAM

P.T. 34; K.W. 0715035, 0403004, 0745005, 0745020, 0745035, 0745055, 0785055

NATIONAL CANCER INSTITUTE

Application Receipt Date: February 21, 1986

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites Small Grants Research applications from interested investigators who meet the eligibility criteria noted below. This RFA is a modified reissuance of RFA 84-CA-07 and 85-CA-05.

I. RESEARCH GOALS AND SCOPE

A Cancer Control Small Grants Research Award is designed to encourage scientists from a variety of academic disciplines to apply their skills to scientific investigations in the field of human cancer control intervention research.

A. Definition and Phases of Cancer Control

Cancer control is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results.

Cancer control research studies are classified into one of five phases which represent the orderly progression noted in the above definition: (I) hypothesis development; (II) methods development and testing; (III) controlled intervention trials to establish cause and effect relationships; (IV) research in defined, human populations; and (V) demonstration and implementation studies. The Division is primarily interested in research on cancer control interventions in Phases II through V.

B. Program Areas

Cancer Control Program areas appropriate for research grants include human intervention research in the following areas:

- prevention (chemoprevention, diet and nutrition, occupation and early detection)
- community oncology (improving application of patient management and continuing care research advances in community settings)

- health promotion sciences (modifying personal, social and lifestyle and health care system factors which contribute to cancer prevention and control)
- smoking prevention and cessation
- cancer control operations research and evaluation
- control applications research (adaption of state and local health agency agency data bases for cancer control planning and evaluation; feasibility testing of interventions in community settings)
- applied epidemiology (using epidemiologic methods to determine the association between exposure to an intervention and its impact on disease)
- epidemiologic, planning and survey studies aimed at developing cancer control interventions

C. Exclusions: Animal studies and studies to determine the efficacy of chemotherapy, surgery, radiotherapy, and other primary treatment interventions are not considered cancer control research under this RFA.

II. ELIGIBILITY

Investigators are eligible to apply for a small grant to support research on a cancer control topic if they are interested in conducting exploratory studies in cancer control research. This includes established researchers from other disciplines, new investigators, and investigators currently enrolled in an accredited doctoral degree program. The only exclusions are those individuals who have been a Principal (or Co-Principal) Investigator on an NCI funded cancer control grant or contract, or a paid staff member on an NCI funded cancer control grant or contract for more than two years. Dissertation research proposals are acceptable as specified in the RFA.

III. MECHANISMS OF SUPPORT

Awards will be made as research grants. Total costs (direct plus indirect costs) must not exceed \$35,000. The duration of support is one year but may be longer (up to two years) if the funding limits noted above are not exceeded. The direct costs for dissertation research should not exceed \$15,000.

IV. INQUIRIES

Copies of the complete RFA and additional information may be obtained from:

Carlos E. Caban, Ph.D.
Program Director for Cancer
Control Research
Cancer Control Science Program
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 4A01
Bethesda, Maryland 20892-4200
Telephone: (301) 427-8735

David C. Postkanzer, M.D.
Cancer Control Science Program
Division of Cancer Prevention
and Control
National Cancer Institute
Blair Building - Room 4A01
Bethesda, Maryland 20892-4200
Telephone: (301) 427-8788

Prospective applicants are strongly encouraged to discuss their ideas with the Program Director to determine whether they fit within the definition and program guidelines of cancer control. APPLICATIONS WHICH, IN THE OPINION OF NCI STAFF, DO NOT FIT WITHIN THE GUIDELINES WILL BE RETURNED WITHOUT REVIEW.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-CA-04

INTERVENTIONS TO IMPROVE THE QUALITY OF SURVIVAL FOR RECOVERED
CHILDHOOD CANCER PATIENTS

P.T. 34; K.W. 0415000, 0715035, 0785170, 0414014

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date:	January 15, 1986
Application Receipt Date:	March 15, 1986
Start Date:	January 1, 1987

I. BACKGROUND

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) announces the availability of a Request for Applications for research projects to develop, implement, and evaluate interventions to address long-term morbidity among survivors of pediatric cancers. Encouraging survival statistics, numerous deleterious physical and psychosocial sequelae have been documented. This RFA encourages research that focuses on approaches to preventing, reversing, or remediating negative outcomes in this population.

This RFA announcement is for a single competition with a specified deadline of March 15, 1986 for receipt of applications.

II. MECHANISM OF SUPPORT

Awards are provided to non-profit organizations and institutions, governments, and their agencies, for-profit organizations, and occasionally to individuals when deemed by the PHS to be consistent with legislative intent and program purposes. Given the relatively small numbers of pediatric oncology survivors, multi-institutional ventures involving groups of researchers, e.g., consortia, may be advantageous in many projects.

NCI plans to support up to two awards under this RFA. Up to a five-year period of support is provided for, with costs for both projects totaling up to \$400,000 for the first year, dependent upon the availability of funds.

III. STAFF CONTACT

Direct all inquiries and requests for the full text of the RFA to:

Carolyn Cook Gotay, Ph.D.
Community Oncology and Rehabilitation Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 7A05
Bethesda, Maryland 20892-4200

Telephone: (301) 427-8708

A more detailed RFA is available upon request from the Institute contact. A letter of intent, while not mandatory, is strongly suggested and should be forwarded to the Institute no later than January 15, 1986. A letter of intent is not binding or a necessary requirement for application, and it will not enter into the review of any application subsequently submitted.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT: RFA

86-CA-05

NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS FOR TREATMENT OF ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

P.T. 34; K.W. 0715120, 0715125, 0415000, 1002045, 1002008, 0710070, 1003002, 0710080, 1003012, 0710100

NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

RFA Availability Date	December 6, 1985
Letter of Intent Receipt Date	January 15, 1986
Application Receipt Date	March 10, 1986

The National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID) jointly announce availability of an RFA for funding of National Cooperative Drug Discovery Groups for Treatment of Acquired Immune Deficiency Syndrome (NCDDG/AIDS). The RFA (available on request) invites applications aimed at the preclinical discovery of effective and curative treatment of AIDS. Scientific approaches to the discovery of effective anti-AIDS treatment appropriate to the RFA may range from interference with infecting virus replication or function to the maintenance or restoration of immune responses. Applications directed to vaccine development or treatment of AIDS-associated diseases (lymphoma, Kaposi's sarcoma, opportunistic infections, etc.) are not invited. Otherwise, scientific approaches to the discovery of effective treatment appropriate to the RFA are broad and limited only by the creativity and ability of the applying group to exploit leads from basic studies in virology, molecular biology, immunology, biochemistry, medicinal and organic chemistry, and pharmacology.

Each NCDDG/AIDS will be assembled by the Principal Investigator to form a multidisciplinary consortium of the various skills needed to successfully design, synthesize, and evaluate, preclinically, treatment entities and strategies for the treatment and cure of AIDS. Inasmuch as it is unlikely that all of the outstanding talents required to exploit fundamental leads from various scientific disciplines will be found in a single institution, each Group is envisioned as being multi-institutional as well. Thus,

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended, 42 USC 241, and 42 USC 282) and administered under PHS grant policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

each NCDDG/AIDS will be assembled by the principal investigator and will consist of a number of Laboratory Programs representing the scientific disciplines required to attain the Group's goal and objectives. The various Laboratory Programs, including that of the principal investigator, may be mobilized from academia, research institutions, or industry. It is expected that the rationale for design of potential treatments, their synthesis, and the preclinical models for their evaluation will originate within the Group and be based on leads from their own and others' fundamental research. Specifically excluded from the Group's activities are activities related to clinical introduction of a new agent; i.e., bulk synthesis and formulation, animal toxicology, and performance of clinical pharmacology and trials.

Awards will be made as Cooperative Agreements. Assistance via Cooperative Agreement differs from the research grant in that the Government component (in this instance, NCI and NIAID) awarding the Cooperative Agreement anticipates substantial involvement during performance. The nature of NCI/NIAID staff participation is described in the RFA. However, the applying Group must define its objectives in accord with its own interests and perceptions of approaches to curative anti-AIDS treatment.

The proposed applicant institution will be responsible for the Group's application. Awards will be made to the Group as a whole and not to individual Laboratory Programs within the Group. The principal investigator's institution will provide a Central Operations Office for the Group. The applicant institution will be responsible for the performance of the entire Group and will be accountable for the funds awarded. The participation of the Government through the NCI/NIAID extramural staff is aimed at facilitating a concerted effort by the Group by making available to the Group biological materials for testing, appropriate existing data bases, and appropriate ancillary testing under existing contracts. The interaction of academic and non-profit research institutions with commercial organizations and Government is expected to favor efficient invention of anti-AIDS treatment and will facilitate their subsequent development to clinical trial.

NCI/NIAID hope to make four to six awards for project periods of five years and have set aside \$3,000,000 total costs (\$1,500,000 from NCI and \$1,500,000 from NIAID) for the initial year's funding.

This RFA is available from:

Dr. John M. Venditti
NCDDG Program Director
Ladow Building - Room 5C03
National Cancer Institute
Bethesda, Maryland 20892

Telephone: (301) 496-8752

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****86-HL-11-L****HYPO- AND HYPERBARIC RESEARCH SUPPORT FACILITIES****P.T. 34; K.W. 0705015, 0705065, 0706040****DIVISION OF LUNG DISEASES****NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Date: April 1, 1986

The Structure and Function Branch of the Division of Lung Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will provide core support for laboratories with existing facilities for hypobaric and hyperbaric research in humans and/or vertebrate animals and an active, peer reviewed research program to expand our knowledge of man's heart, lung or blood function at simulated altitude and/or depth; peer reviewed studies into both hyperbaric and hypobaric aspects of heart, lung, or blood function must be funded at the time of the award.

A letter of intent is requested by February 1, 1986, and the deadline for receipt of applications is April 1, 1986. The earliest award date for successful applications will be in September 1986. Requests for copies of this RFA should be addressed to:

Everett E. Sinnett, Ph.D.
Structure & Function Branch
Division of Lung Diseases, NHLBI
5333 Westbard Avenue - Room 6A07
Bethesda, Maryland 20892

Telephone: (301) 496-7171

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-AG-01

MECHANISMS RESPONSIBLE FOR AGE-RELATED INCREASE IN BLOOD PRESSURE

P.T. 34; K.W. 0715115, 0785055, 0710095, 0710100, 1002034, 0785050, 1002019, 0710010, 0755030

NATIONAL INSTITUTE ON AGING

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: April 16, 1986

The National Institute on Aging (NIA) and the Division of Heart and Vascular Diseases (DHVD), National Heart, Lung, and Blood Institute (NHLBI) announce the availability of a request for applications (RFA) on the above program.

The proposed program "Mechanisms Responsible for Age-Related Increase in Blood Pressure" will provide support for research project grants for a period of up to five years after which it is anticipated that the grantees will continue to compete through regular support mechanisms. The number of grants awarded will vary according to available funds. Each application should focus on investigations seeking to elucidate mechanisms of blood pressure regulation which account for age-related increases in blood pressure associated with industrialized societies. Both human and animal studies are welcome. Among the disciplines and skills appropriate for this research program are those of basic and clinical sciences such as epidemiology, nutrition, biochemistry, pharmacology, physiology, pathology, endocrinology, genetics, gerontology, and behavioral sciences.

Requests for copies of the RFA should be addressed to:

Lot B. Page, M.D.
National Institute on Aging
Building 31 - Room 5C21
9000 Rockville Pike
Bethesda, Maryland 20892

or

John B. Dunbar, Dr. P.H.
Hypertension and Kidney Diseases Branch
National Heart, Lung, & Blood Institute
Federal Building - Room 4C12
Bethesda, Maryland 20892

Telephone:
(301) 496-1033

(301) 496-1857

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-HL-15-L

MINORITY SUMMER PROGRAM IN PULMONARY RESEARCH

P.T. 34, FF; K.W. 0715165

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: August 1, 1986

The Prevention, Education, and Research Training Branch of the Division of Lung Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will encourage qualified minority school faculty members and graduate students to develop interests and skills in research in pulmonary diseases at established pulmonary training centers. It will also stimulate pulmonary research by offering minority school faculty members and students the opportunity to enhance their research capabilities at domestic institutions which offer superior opportunities in this area.

Requests for copies of the RFA should be addressed to:

Research Training Program
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 640
Bethesda, Maryland 20892

Telephone: (301) 496-7668

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATION: (RFA)

86-HL-07-B

COMPREHENSIVE SICKLE CELL CENTERS

P.T. 04; K.W. 0715040, 0750010, 0745020, 0502017, 0403004, 0710030, 0785035

DIVISION OF BLOOD DISEASES AND RESOURCES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: September 15, 1986

The Sickle Cell Disease Branch, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, (NHLBI) announces its intent to support on a competitive basis ten Comprehensive Sickle Cell Centers, each capable of a wide range of activities encompassing basic and clinical research as well as demonstration activities in education, diagnosis and counseling services to the community. This announcement reaffirms the interest of the NHLBI in continuing to employ the Center program to extend the "state of the art" of sickle cell disease research, education, diagnosis and counseling, and to exploit the synergistic interaction of these efforts. Copies of the RFA, 86-HL-7-B, may be obtained from staff of the NHLBI.

The purpose of Comprehensive Sickle Cell Centers is to focus resources, facilities and manpower in a coordinated effort to solve problems of high priority related to sickle cell disease. In the setting of a Center, it should be possible to coordinate efforts in fundamental and clinical research, clinical applications, education and demonstration programs and to bring the results from each component promptly to bear on the others.

Request for copies of the RFA should be addressed to:

George B. Riley, Ph.D.
Health Scientist Administrator
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 508A
Bethesda, Maryland 20892

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****86-DE-01****RESEARCH CENTERS IN ORAL BIOLOGY (RCOB)****P.T. 04; K.W. 0745010, 0710070, 1002027, 1002045, 1002019, 1002006, 0710095, 0710085****NATIONAL INSTITUTE OF DENTAL RESEARCH**

Application receipt date December 1, 1986

I. BACKGROUND INFORMATION

The National Institute of Dental Research (NIDR) announces the availability of a request for applications (RFA) for the above program. These centers will provide support for multidisciplinary research centers that bring together the diverse resources of an institution to investigate important basic science and related applied problems relevant to oral health and disease.

II. RESEARCH GOALS AND SCOPE

The RCOB program's primary goal is to expand the scientific base which underlies the nation's capability to control oral diseases and disorders and to improve oral health. The full range of biomedical research from basic to clinical may be supported under the RCOB mechanism. Support will be provided for collaborative multidisciplinary studies in basic biomedical research areas and selective applied extensions to problems relevant to the mission of the NIDR. Some examples of basic biomedical science research areas which are particularly appropriate for study under the RCOB program include: Immunology; Microbiology/Virology; Genetics, Developmental Biology; Tissue Structure and Function; Tissue Repair and Regeneration; Salivary Glands and Secretions; Nutrition; Neurobiology. Support will not be provided for a RCOB that has as a single focus a categorical or thematic area already targeted by NIDR for center support.

III. DUE DATE AND IDENTIFICATION OF CONTACT POINT

The due date for the receipt of applications is December 1, 1986. Requests for copies of the RFA or for additional information should be directed to:

Dr. Aaron Ganz
Special Assistant for Centers
and Special Programs
National Institute of Dental Research
Extramural Programs
Westwood Building - Room 510
5333 Westbard Avenue
Bethesda, Maryland 20892

Telephone: (301) 496-6324

ANNOUNCEMENT

DISEASE MECHANISMS IN IMMUNOLOGIC RENAL DISEASE

P.T. 34; K.W. 0705040, 0710075, 0785095, 0710065, 0710060, 0765035, 1003002, 1002004, 1002008, 1002019, 0785055, 0755020

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

I. PURPOSE

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDDK) invites qualified investigators to submit research grant applications for the support of investigations to examine the role of the immune system in renal injury by expanding interdisciplinary research efforts that will lead to an elucidation of immunopathogenetic mechanisms and define new avenues showing promise for correcting, treating and/or preventing immunologic renal disease. It is hoped that this announcement will stimulate a sustained growth in the number of applications involving immune mechanisms and mediators of inflammation in renal disease submitted to NIH in the future.

II. DISCIPLINE AND EXPERTISE

The interdisciplinary nature of such renal studies will require collaboration among experts in areas such as the major disciplines of immunology, (cellular immunology, immunogenetics, immunochemistry, immunopathology and immunopharmacology), nephrology, renal physiology and pathophysiology, biochemistry, pathology, molecular/cellular biology, genetics and epidemiology.

III. BACKGROUND

Evidence accumulated during the last few decades implicates immunologic factors in a variety of renal diseases, in particular the glomerulonephritides and interstitial nephropathies. The majority of immunologically-mediated glomerular diseases are associated with deposits of immuno-reactants (e.g. immunoglobulin, complement components) in glomeruli in both primary (e.g., membranoproliferative GN) and systemic (e.g., lupus nephritis) diseases. The immunologic mechanisms thus far defined involve deposition of immune complexes from the circulation or their formation in situ by reaction of circulating antibody with native or "planted" glomerular antigens.

This program is described in the Catalog of Federal Domestic Assistance No. 13.849, Kidney, Urologic, and Hematologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

These mechanisms appear to constitute the primary pathogenetic forms of mechanisms of immune renal injury, but it is clear that additional secondary mechanisms are involved. The role of mediators such as complement, leukocytes, platelets, prostaglandins, lymphokines, coagulation and toxic oxygen metabolites may be important in determining histologic and clinical expression of immune renal diseases. The influence of immune regulation (antigen-specific and anti-idiotypic) requires further evaluation and integration into overall schemes of immunopathogenesis. The role of cellular immunity in glomerular and interstitial diseases requires further definition. Examples are minimal change GN and the nephritis of systemic vasculitis. Lymphoid cell infiltrates in renal interstitial tissue also suggest that direct cell mediated immune injury may be a component of many forms of nephritis, with or without associated antibody deposition. In addition, the fundamental mechanisms of cell mediated immune responses which underlie the humoral antibody and/or immune complex disturbances of the more common nephropathies require further exploration.

IV. OBJECTIVES AND SCOPE

This solicitation is prompted by a recognized need for an expanded research effort to gain greater insight into the immunopathogenetic mechanisms that may cause renal injury and to define mechanisms for arresting, treating and/or preventing immunologic renal disease.

New methodologies and technologies, such as monoclonal antibodies, cell culture and gene cloning are emerging, which should be exploited in the renal field. Making use of these advances should facilitate investigations in the following areas.

- Investigation of host factors (genetic and immunologic) that predispose to the development of immune complex disease glomerulonephritis and other forms of immune-mediated renal injury; in particular, it is now possible to perform studies that may reveal more significant associations between MHC haplotypes (extended haplotypes) or HLA-D gene products (through restriction endonuclease analyses) than was hitherto possible.
- Studies to define the role of cell-mediated injury in the pathogenesis of glomerulonephritis, such as minimal change disease and certain forms of crescentic glomerulonephritis, and various forms of interstitial nephritis.
- Studies of factors favoring the deposition or in situ formation of immune complexes within the glomerulus.
- Studies designed to identify the antigens involved in presumed immune complex glomerulonephritis; in particular, this by immunization of mice with glomeruli from kidneys with immune complex diseases, and by screening of clones for reactivity with particular forms of glomerulonephritis (membranous, proliferative etc.).
- Development of additional animal models in which cell-mediated injury is demonstrable.

- Studies to better define the role of lymphoid cells (i.e., T suppressor and helper cells, cytotoxic T cells, subsets of B cells, natural killer cells, etc.) which by immunoregulatory imbalance may cause disordered humoral immune responses.
- Development of new markers and new ways of assessing functional activity of lymphoid cells within glomerular or tubulo-interstitial inflammatory infiltrates.
- Studies of cellular and soluble mediators which influence the expression of immunologic renal disease.
- Studies of the composition, structure and function of glomerular basement membrane in normals and in subjects with immunologically mediated glomerular disease.
- Studies of the mechanisms of inflammatory damage to the glomerulus in immunologic renal disease (e.g. the role of lysosomal enzymes, eicosanoids and reactive oxygen species).
- Studies of nonimmunologic mechanisms (e.g., alteration of glomerular hemodynamics that may contribute to glomerular disease).
- Studies identifying the role played by the above immunologic and non-immunologic mechanisms of renal damage in human glomerular and tubulo-interstitial disease.
- Other basic laboratory or clinical studies which have relevance to immunologic basis of renal disease.

V. MECHANISM OF SUPPORT

Although this solicitation is included in the NIADDK's funding plan for Fiscal Year 1987, the award of grants in response to the Program Announcement is contingent upon receipt of appropriated funds. The specific number to be funded will depend upon the merit of the applications and funding is expected to begin December 1, 1986.

All PHS and NIH Grant policies governing regular research project grants, including cost sharing, apply to applications received in response to this Program Announcement.

VI. REVIEW PROCEDURES AND CRITERIA

Assignment of Applications

Applications will be received by the National Institutes of Health, Division of Research Grants (DRG), referred to an appropriate Study Section for scientific merit review, and assigned to NIADDK for possible funding, unless programmatic considerations indicate more appropriate assignment to another Institute. These decisions will be governed by normal DRG Referral Guidelines.

Review Procedures

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research applications, and in accord with the usual National Institutes of Health peer review procedures. Applications will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (Study Section), and then by the National Advisory Council of the NIADDK. The review criteria customarily employed by the National Institutes of Health (NIH) for regular research grant applications will prevail.

VII. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. The phrase **"PREPARED IN RESPONSE TO NIADDK KIDNEY PROGRAM ANNOUNCEMENT - DISEASE MECHANISMS IN IMMUNOLOGIC RENAL DISEASE"** should be typed in space #2 on the first page of the application.

VIII. APPLICATION RECEIPT DATES

Applications will be accepted in accordance with the usual NIH receipt dates for new applications. Deadline dates: February 1, June 1, and October 1.

The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20892

For further information, investigators are encouraged to contact the following individual:

M. J. Scherbenske, Ph.D.
Assistant to the Director for Administration
Renal Physiology/Pathophysiology
Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
5333 Westbard Avenue
Westwood Building - Room 621
Bethesda, Maryland 20892

Telephone: (301) 496-7458

ANNOUNCEMENT

BLOOD CELL SURFACE ANTIGENS RELATED TO DISEASE

P.T. 34; K.W. 0750010, 0710060, 0790005, 0715015, 1002004

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The Division of Blood Diseases and Resources (DBDR), National Heart, Lung, and Blood Institute (NHLBI) encourages grant applications on the characterization and biological significance of blood cell surface antigens, particularly as they relate to the structural integrity of the cell, to specific cell functions, and to specific disease processes. Until recently, the major reasons for identifying blood group antigens and antibodies has been their importance in assuring safe and effective blood transfusions. In recent years, however, clinical information regarding the relation of blood cell antibodies and antigens to disease has accumulated, as has knowledge of blood cell membrane structure and function. For instance, red cell antigens can serve as targets for selected autoantibodies in various diseases. It appears that a similar situation exists for platelets and neutrophils--specifically, that tissue-specific antigens can serve as receptors for autoantibodies, which may result in immune destruction of the blood cells, leading to thrombocytopenia or neutropenia. Many red blood cell antigens are associated with diseases as indicated by their loss during the disease process or by an increase in the level of corresponding antibody. In addition, it appears that some red blood cell antibodies recognize antigenic specificities that are also found on microorganisms, suggesting that blood group antigens are structurally similar to surface determinants found elsewhere in nature. Some of the most exciting work relates to the Duffy antigen system. Red blood cells which lack Duffy antigens (Duffy a- b-) are resistant to parasitization by *Plasmodium knowlesi* and it appears that Duffy determinants are required for parasitic invasion by *Plasmodium vivax*.

As knowledge of blood cell membrane structure and function has accumulated, so has clinical information regarding blood cell antibodies, antigens, and their relationship to many disease states. It seems quite possible that blood cell antigens play important roles in membrane integrity or cell surface function, or both. The state of knowledge and techniques is such that valuable new information about cellular structure and function would be forthcoming as a result of this solicitation. Thus, the overall goal of this solicitation is to increase our understanding of the nature and function of these cell surface determinants. Studies involving erythrocytes, leukocytes or platelets are encouraged.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372, or to Health Systems Agency review.

Applicants should use the regular research grant application (PHS 398). There are three receipt dates each year for new applications: February 1, June 1, and October 1. All applications will be assigned by the Division of Research Grants (DRG) for review according to the NIH process for regular research grant applications. Secondary review will be by the National Heart, Lung, and Blood Advisory Council. Applications recommended for approval will compete for available funds with all other approved applications assigned to the NHLBI. If applications are not available at the institution's business office or central application control office, an individual copy may be requested by writing to DRG, NIH. In order to identify the application as a response to this program announcement, check "yes" on Item 2 of the application face page with the title **"BLOOD CELL SURFACE ANTIGENS RELATED TO DISEASE."** The original and six copies of the application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20892

Requests for additional information or questions regarding this program may be directed to:

Dr. Luiz H. Barbosa
Blood Resources Branch
Division of Blood Diseases and
National Heart, Lung, and Blood Institute
Federal Building - Room 5C10
Bethesda, Maryland 20892

Telephone: (301) 496-1537

ANNOUNCEMENT

CARDIOVASCULAR STUDIES IN PARTICULAR ANIMAL MODELS

P.T. 344; K.W. 0715115, 0715040, 0765020, 0710095, 1002019, 0785170, 0404000, 0735015, 0710100, 0785165, 0785050, 0705055, 0765035

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Heart, Lung, and Blood Institute (NHLBI) announces its intent to award small grants for cardiovascular research studies of a small or pilot nature using the nonhuman primate resource colonies supported by the Division of Heart and Vascular Diseases (DHVD).

The program objectives are:

- 1) To conduct research on factors involved in the pathogenesis of atherosclerosis or of hypertension in nonhuman primate models that delineate particular aspects of these disorders.
- 2) To study pediatric and developmental aspects of atherosclerosis or hypertension in such models.

An additional objective of the program is to allow investigators from institutions that have a need but do not have the resources, to conduct cardiovascular studies in the nonhuman primate. This will be accomplished through the use of the resources, facilities, and collaborative opportunities available at the existing DHVD supported colonies.

It is hoped that these small or pilot studies will lead to more clearly defined, efficiently executed regular research grant applications using the nonhuman primate as a model for studies in such areas as metabolism, nutrition, genetics, pediatrics, behavior, instrumentation, pharmacology, pathology, lesion regression, endocrine systems, the central nervous system, electrolyte transport and the microcirculation, as well as other studies related to the pathophysiology of atherosclerosis and hypertension.

The award will provide a maximum of \$50,000 (direct costs) over a period not to exceed two years for technical assistance, supplies, small equipment, shipping, subcontract costs (to include fee-for-service costs at the primate facilities) and travel required by the project. (It is anticipated that most of the grants in this program will not require the full two year time frame or the maximum costs.)

This program is described in the Catalog of Federal Domestic Assistance, No. 13.837. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372, or Health Systems Agency review

Application Submission and Review

Application receipt dates are the regular receipt dates in 1986 of February 1, June 1, and October 1. Applications will be reviewed by Study Section as assigned by the Division of Research Grants. Adherence is required to the Federal Animal Welfare Regulations and to Interagency Research Animal Committee Guidelines for the use of the nonhuman primate.

Inquiries

For inquiries and copies of a more detailed program description and application instructions please contact:

Nanci C. Parsons
Lipid Metabolism-Atherogenesis Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4A08
Bethesda, Maryland 20892

Telephone: (301) 496-3271

ANNOUNCEMENT

LARGE GRANT SUPPORT PROGRAMS - GENERAL PROGRAM ANNOUNCEMENT

P.T. 04, 34; K.W. 0745010, 0710030, 0785040

NATIONAL INSTITUTE OF DENTAL RESEARCH (NIDR)

I. INTRODUCTION

The National Institute of Dental Research (NIDR) has served as a national resource and focal point for the support of research and research training relevant to oral health and disease since its establishment almost 40 years ago. During those years the NIDR has utilized a variety of research support mechanisms in order to make research and research training opportunities available to the extramural community. The regular research project grant (R01) has been a major mechanism for support of individual projects, while program project grants (P01) and center grants (P50) have been used to support teams of investigators conducting multidisciplinary, closely related projects. The purpose of this announcement is to inform the dental research community about the NIDR's current plans for program projects and center grants. These grants will be used to support the full range of basic, applied, and clinical research through assisting universities and other research institutions to strengthen their multidisciplinary research capabilities.

By informing the dental research community of these plans, the NIDR hopes to both stimulate meritorious research proposals that will advance dental research and provide information that will assist potential applicant institutions in developing their own plans and future application strategies. It must be cautioned, however, that the realization of these plans is dependent upon the availability of necessary authority and resources which are provided on an annual fiscal year basis.

II. LARGE GRANT MECHANISMS TO BE UTILIZED BY THE NIDR

A. Research Program Projects (P01's)

1. Description:

The research program project grant provides support for a group of discrete projects which focus on a single major research area or unifying theme. A program project generally involves the organized efforts of several investigators who are conducting research projects designed to elucidate various aspects or components of this research area or theme. Each research program project is headed by a program director and provides support for the individual projects. It also supports certain common resources, including laboratory and animal facilities, research services, clinical components, and administrative assistance. Funding for support services used jointly is called "core support".

Program project grants are typically investigator-initiated research proposals that can be developed at any time and submitted for the regular grant receipt dates of February 1, June 1, and October 1.

Approved PO1 grants compete directly on the basis of scientific merit with other investigator-initiated applications, most notably the traditional research grants (KO1). Five years of support may be requested and subsequent competing continuation grant applications can be submitted.

2. Current and Planned Use:

Research program project grants have been utilized by the NIDR since 1962. Support has varied from a high of 28 in 1969 to a low of nine in 1978. In FY 1984, the NIDR supported 10 research program project grants. The NIDR anticipates an expansion in its use of this support mechanism and intends to issue shortly a program announcement encouraging submission of additional research program project grant applications.

B. Center Core Grants (P30's)

1. Description:

The center core grant is a mechanism of support intended to enhance and extend the effectiveness of a group of related projects and investigators that are already funded through other mechanisms such as research project grants or research program projects. This mechanism is appropriate for those institutions that already have an established base of dental research excellence. The center core grant provides support for resources and facilities to be shared by the individually-supported project grantees in order to enhance research quality and productivity, promote communication and collaboration, stimulate research ideas, and enhance the cost effectiveness of the research program.

2. Current and Planned Use:

The NIDR has not previously used this support mechanism, but plans to announce the availability of core grants in the near future. This specific program announcement will solicit applications for this award from the dental research community. Specific guidelines with respect to the award itself and the peer review process will appear in the announcement.

C. Research Center Grants (P50's)

1. Description:

The research center grant provides in one award support for both research projects and the core services used by those projects. The full range of research from very basic to clinical may be supported under the research center grant mechanism. It is an institutional award made in the name of a center director. Activities supported under a research center grant should involve multidisciplinary research on a specific disease entity or on one or more basic science areas relevant to the mission of the NIDR. A secondary objective of the research center grant is the creation of a research environment that will attract new

investigators into oral health research and contribute to the development of young investigators. Research center grants are developed in response to a specific announcement of programmatic needs by the NIDR. Applicant institutions must possess scientific personnel and institutional resources capable of providing a strong research base on the field(s) specified. Applications are awarded competitively for a five year grant period.

2. Current and Planned Use:

The NIDR began using the research center grant mechanism in the late 1960's to fund four dental research institutes and centers (DRICs). A fifth DRIC-type center was funded in 1972. All five are still being supported. In addition, by the beginning of FY 1985, the NIDR was supporting six specialized categorical research centers, three periodontal centers and three dental caries centers, utilizing the research center grant mechanism.

The NIDR intends to continue to use the research center grant mechanism to support both noncategorical and categorical/thematic multidisciplinary research. Emphasis will be on open competition. In order to accomplish that, the NIDR plans to have common grant termination dates for all future research center grants supporting similar areas of research and similarly will bring existing categorical and noncategorical centers into phase. Once this has been accomplished, all center awards will be made for an initial period of five years and the continuation of support beyond the initial project period will be possible only if the NIDR reissues an RFA and the applicant institution is successful in the ensuing open competition.

As a first step toward achieving these goals, the NIDR is issuing a request for application (RFA) for multidisciplinary research centers with funding to begin in FY 1987. The notice of availability of this RFA appears in the current issue of the NIH Guide. These centers will be entitled Research Centers in Oral Biology (RCOB). A subsequent action will establish common starting and termination dates for the periodontal research centers. (The three dental caries research centers have common termination dates.) The NIDR will continue with its plans for additional categorical/thematic centers and is anticipating funding one or more new centers in FY 1987.

III. GENERAL DISCUSSION

The NIDR has utilized its existing constituted advisory bodies, special ad hoc consultant groups, and has consulted broadly with the dental research community concerning the future use of its large grant program. In announcing its plans to offer a broadened large grant program, the NIDR intends to structure these mechanisms to provide qualified applicants the maximum opportunity to develop creative approaches to dental research problems.

The NIDR is fully committed to ensure that there is full and open competition among all eligible institutions for support under the various large grant programs. The NIDR is also committed to ensure that all large grant applications undergo uniformly rigorous merit review and that projects of only the highest merit are funded.

Interested investigators and institutions are advised to contact the NIDR to discuss their interest in bringing teams of investigators into collaborative relationships and to explore which large grant mechanism or mechanisms might be the most appropriate to meet their objectives.

Initial contact should be made to:

Dr. Aaron Ganz
Special Assistant for Centers
and Special Programs
Extramural Programs
National Institute of Dental Research
Westwood Building - Room 510
Bethesda, Maryland 20892

Telephone: (301) 496-6324 or 7807

ANNOUNCEMENT

NIDR MINORITY RESEARCH SUPPLEMENT PROGRAM

P.T. 344, FF; K.W. 0745010, 0710030

NATIONAL INSTITUTE OF DENTAL RESEARCH

I. DESCRIPTION

The National Institute of Dental Research (NIDR) will provide support for under-represented minority researchers through the Minority Research Supplement Program (MRSP). A minority investigator is defined as a Black, Hispanic, Native American, Asian, or Pacific Islander.

Institutions with NIDR research grants of all types (R01's, P01's, P50's) and interested in including under-represented minority investigators in such research endeavors may submit a supplemental grant application for this purpose. Meritorious applications will be funded as supplements to the existing award.

II. OBJECTIVE

The MRSP will provide supplemental funds to NIDR-supported principal investigators for the purpose of increasing the number of under-represented minorities actively pursuing research objectives relevant to the funded project and to the mission of NIDR.

III. PROJECT EVALUATION AND REVIEW CRITERIA

NIDR staff will evaluate applications requesting supplemental support under this announcement using as criteria the degree to which:

- o The research activities proposed under the supplemental request fit within the scientific scope, and the time and resources available for the funded project.
- o The research training, experience and potential of the candidate are sufficiently strong to provide assurance that the research objectives proposed will be accomplished.
- o The principal investigator and the minority candidate demonstrate a clear understanding of the objectives of the MRSP.

This program is described in the Catalog of Federal Domestic Assistance No. 13.845, Dental Research Institutes. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The initial review of the administrative and scientific aspects of each proposal will be conducted and managed by the staff of the Extramural Programs, NIDR. Any application requiring additional technical merit review will be deferred for traditional peer review before any further consideration by NIDR. All recommendations will be presented for concurrence to the National Advisory Dental Research Council.

IV. ELIGIBILITY

Any institution with an active NIDR research grant, program project or research center award is eligible to submit a supplemental application on behalf of a principal investigator for the purpose of including under-represented minority researchers in the project.

- A. Under-represented Minority Investigator - The minority investigator may be affiliated with the applicant institution or with some other institution. The investigator is expected to provide a complete curriculum vitae which includes a list of research publications and other evidence of meritorious scientific achievements. The program is not intended to pay stipends for student trainees or to support candidates with insufficient research backgrounds. The minority investigator must be willing to devote at least 50% of his/her time to the research project.
- B. Research Project - The proposed research project must be closely related to the currently funded research grant. It may represent an increased effort in an already approved objective of the original research project or it may propose a new objective closely related to those already approved. The nature of the proposed research should provide the minority investigator an opportunity to contribute intellectually to the program and to enhance his/her own research skills. The scope of the proposed research project should usually be comprehensive enough to require at least two years for completion and the supplemental application should include such a research plan and projected budget sheets. A one-year application may be acceptable with appropriate justification. No MRSP applications will be accepted in the final year of the current award.

V. FUNDING

Funding will be provided in accordance with the usual NIH policy for supplements. Awards will be issued on an annual basis. Continuing support for the second (or subsequent) year will depend upon approval of a satisfactory annual progress report and a proposed budget from the minority investigator submitted with the principal investigator's non-competing continuation application. Funding for the supplement is always contingent on funding of the parent grant. Each annual supplemental budget shall not exceed \$40,000 in direct costs and may not include equipment. Supplemental awards made under this program are for the sole purpose of facilitating participation by minority investigators as described above. Applications should meet one of the following deadlines: November 1, March 1, July 1.

VI. HOW TO APPLY

The principal investigator and the minority investigator should submit a supplemental grant application through the institution on the Standard Form PHS 398, limited to the following: (1) face page, at the top of which the applicant must designate the grant number of the active grant and specifically state "Minority Investigator Supplement"; (2) budget page; (3) a biographical sketch of the minority researcher; (4) an outline of the proposed research project as it relates to the parent grant; and (5) as part of the Significance section, the application should include a statement from the minority investigator outlining his/her research objectives and career goals and a statement from the principal investigator describing how this research experience will expand the capabilities and foster the independent career of the minority investigator.

The original and four (4) copies of the application should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20892

Two copies should be sent under separate cover to:

Dr. Aaron Ganz
Special Assistant for Centers
and Special Programs
Extramural Programs
National Institute of Dental Research
Westwood Building - Room 510
Bethesda, Maryland 20892

Telephone: (301) 496-6324

ERRATUMANNOUNCEMENTTHE NCI OUTSTANDING INVESTIGATOR GRANT

P.T. 34; K.W. 0715035, 0710030

NATIONAL CANCER INSTITUTE

In Vol. 14, No. 10, September 13, 1985 issue of the NIH Guide for Grants and Contracts, Page 30, Part V - HOW TO APPLY, the second bullet is incorrect. The correct statement should read as follows:

- o "Application for this award should be made on form PHS 398 (Rev. 5/82) in accordance with instructions in this Announcement. These applications are available in the business or contracts offices at most academic or research institutions, or from:

Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20892"

ANNOUNCEMENT

BIOLOGICAL MECHANISMS OF OMEGA-3 FATTY ACIDS IN HEALTH AND DISEASE STATES

P.T. 34; K.W. 0710090, 0715040, 0765025, 0710070, 0790010

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

NATIONAL EYE INSTITUTE

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

NATIONAL INSTITUTE ON AGING

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

NATIONAL INSTITUTE OF MENTAL HEALTH

I. BACKGROUND INFORMATION

The National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration invite grant applications for the support of research to elucidate the biological mechanisms by which a seafood diet or the ingestion of fish oils influence health and modulate a number of disease processes. A number of studies have indicated a role for fish or fish oils in prostaglandin metabolism, autoimmune disease, thrombosis and deaths from cardiovascular disease. Most investigators have reached the conclusion that some special food component, probably the omega-3 polyunsaturated fatty acids, which is common to fish, arctic mammals, and cod liver oil must be important.

Data from research on the effects of omega-3 polyunsaturated fatty acids derived from seafoods were reviewed at the Conference on the Health Effects of Polyunsaturated Fatty Acids in Seafoods held June 24-26, 1985, in Washington, D.C. and sponsored by the Nutrition Coordinating Committee of NIH; the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration, Department of Commerce; and the National Fisheries Institute. The conference had two objectives:

- (1) To review the research data on: the health effects of polyunsaturated fatty acids in seafoods in terms of the impact of omega-3 fatty acids on eicosanoid formation; thrombosis and atherosclerosis; lipoproteins and atherosclerosis; immunology and inflammation; and the role of docosahexaenoic acid in membrane function and metabolism.
- (2) To develop a research agenda to determine the spectrum of the health effects of polyunsaturated fatty acids of seafood origin in the American diet.

Information presented at the conference clearly indicated the important role of omega-3 fatty acids in the modulation of human metabolism and their potential role in the prevention and treatment of a number of diseases of public health

importance, including cardiovascular diseases, cancer, asthma, certain forms of arthritis, inflammatory and autoimmune processes, etc. These areas of research are also of interest to the U.S. Malnutrition Panel of the U.S. Japan Cooperative Medical Science Program.

II. RESEARCH OBJECTIVES AND SCOPE

Grant applications are solicited to elucidate the role of seafood and fish oils in health and disease. Special but not exclusive emphasis is placed on clinical research and the application of modern techniques to establish the mechanisms through which these dietary components produce the observed results. Multidisciplinary collaborations are encouraged. Suggested areas of research are presented below, but should not be viewed as constraints. Other research proposals, in areas not mentioned below, that are aimed at establishing a clear understanding of the mechanisms through which omega-3 fatty acids or other components in seafoods influence metabolic processes, and to determine the applicability of this family of compounds or materials to the prevention and treatment of disease are also sought.

A. Eicosanoid Formation and Metabolism

A number of fundamental questions regarding the relation of omega-3 fatty acids to eicosanoid formation remain unanswered. Research is needed on: the mechanism through which these fatty acids modulate eicosanoid synthesis (do they form omega-3 derived eicosanoids or slow the conversion of omega-6 fatty acids to eicosanoids); the benefits and side-effects of specific eicosanoids; the relation of the action of eicosanoid inhibitors, e.g., aspirin, to that of omega-3 fatty acids on eicosanoid formation; the appropriate compositions, forms, and types of test materials; and the appropriate metabolites and analytical procedures to be used for the biochemical monitoring of clinical studies.

B. Thrombosis and Atherosclerosis

The influence of eicosapentaenoic acid (EPA) on prostanoid production and the associated physiological effects, e.g., bleeding parameters, platelet aggregation, and on cardiac function requires elucidation. For example, the discrepancy between the time course of change in fatty acid composition of platelet phospholipids with incorporation of EPA and the time course of changes in bleeding time and platelet function in vitro as well as effects of EPA on the mechanical properties of atheromatous plaques are not understood. The biological effects and effectiveness of PGI₃ and TXA₃, the effect of omega-3 fatty acids on platelet serotonin production and release, and the establishment of appropriate doses, forms, and purity of omega-3 fatty acids for clinical trials all require further research.

C. Plasma Lipids and Lipoproteins

Omega-3 fatty acids have been shown to effect lipoprotein metabolism in humans, apparently by decreasing production of VLDL rather than through alteration of receptor mediated removal of LDL that results from the incorporation of omega-6 fatty acids in the diet. It has also been reported that fish oils promote the clearance of chylomicrons and VLDL. These effects and the underlying mechanisms require further study, as do the

possible approaches utilizing meals of fatty fish or various forms of purified fish oils and their derivatives for disease prevention and treatment.

D. Immunology and Inflammation

Cellular effects of omega-3 fatty acids need to be determined for as many different cells as possible, especially polymorphonuclear leukocytes of the neutrophil class, monocytes, macrophages (possibly of pulmonary origin), and T and B lymphocytes. These effects need to be assessed by activation of these cells per se, and in response to trans-membrane probes and the calcium ionophore. In addition, it is critical to assess the functional responses of each cell type individually and in combination with lymphocytes, so that there can be some appreciation of the effects of fish-oil enriched fatty acids on immune regulation as well as on specific aspects of the host inflammatory response. Of paramount importance in these regards are detailed biochemical and cell biological studies to define the mechanism of effect of omega-3 fatty acids on specific biochemical and biological responses of immune cells.

E. Cell Membrane Function and Metabolism throughout the Life Cycle

The current state of knowledge regarding specific roles for classes of phospholipids and fatty acids in cell membrane function is limited. Research has demonstrated that photoreceptor cell membranes in the retina contain an unusually high content of polyunsaturated fatty acids. Rats raised from weanling on an essential fatty acid deficient diet exhibit changes in the electroretinogram which appear to be related to depletion of polyunsaturates from the photosensitive retinal membranes. In addition, when rats fed the deficient regimen subsequently had their diet supplemented with linolenic acid (18:3 omega-3) the electrical activity of the photoreceptors increased toward normal values. This suggests that essential fatty acids and their anabolic products may be important in photoreceptor function, but their exact role remains to be elucidated. Moreover, when the polyunsaturated lipids of these specialized biological membranes become altered by oxidation they may become cytotoxic. This change in fatty acid composition may alter the structure and function of retinal photoreceptors and/or the central visual system by affecting membrane fluidity and permeability, by altering the activity of membrane-bound enzymes, or by other mechanisms which are not yet understood. The findings suggest that dietary omega-3 fatty acids are essential for normal prenatal and postnatal development of the brain.

Other issues that require urgent attention include: the origin of tissue 20: and 22:omega-3 fatty acids (are they derived primarily from dietary sources or are they formed in vivo from other fatty acids such as 18:omega-3); are requirements for omega-3 fatty acids different at various stages of the life cycle; the elucidation of the pathways of enzymatic oxidation and hydroxylation of omega-3 fatty acids; the identification of cofactor requirements, if any; and the role of the liver in the metabolism of omega-3 fatty acids. Several pathological conditions have been associated with changes in brain tissue levels of 22:6 omega-3 fatty acid. Improved techniques to follow the relevant metabolic processes in vivo are needed, particularly in regard to the role and function of these lipids in neural tissues during development and throughout the life cycle.

III. MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid. The regulations (Code of Federal Regulations, Title 42, Part 52 and Title 45, Part 74) and policies that govern the research grant programs of the Public Health Service will prevail. The award of grants pursuant to this announcement is contingent upon ultimate receipt of appropriated funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

- A. Assignment of Applications: Applications will be received by the Division of Research Grants (DRG), NIH, referred to an appropriate study section/review committee for scientific review, and assigned to individual Institutes for possible funding. These decisions will be governed by normal programmatic considerations specified in the DRG Referral Guidelines.
- B. Review Procedures: Applications in response to this announcement will be reviewed on a nationwide basis in competition with other applications received in the same review cycle, and in accord with the usual National Institutes of Health/Alcohol, Drug Abuse and Mental Health Administration's peer review procedures. They will first be reviewed for scientific and technical merit by an initial review group composed mostly of non-Federal scientific consultants (study section/review committee). Following study section review, the application will be evaluated by the appropriate Institute Advisory Council or Board with respect to the adequacy of the technical merit review and the program relevance of the research proposed. The review criteria customarily employed by the NIH/ADAMHA for regular research grant applications will prevail.
- C. Deadlines: Applications will be accepted in accordance with the usual receipt dates for new applications:

February 1

June 1

October 1

V. METHOD OF APPLYING

Applications should be submitted on form PHS 398 which is available in the business or grants and contracts office at most academic and research institutions, or on form PHS 5161 for state and local governments. The phrase **"PREPARED IN RESPONSE TO NIH/ADAMHA OMEGA-3 FATTY ACID PROGRAM ANNOUNCEMENT"** should be typed into item 2 of the first page of the application.

The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20892

Prospective applicants are urged to contact program staff listed below for further information and assistance.

National Institute of Arthritis,
Diabetes, and Digestive and
Kidney Diseases

Van Hubbard, M.D., Ph.D.
Westwood Building - Room 3A18B
NIADDK, NIH
Bethesda, Maryland 20892
(301) 496-7823

National Institute of Neurological
and Communicative Disorders
and Stroke

Eugene Streicher, Ph.D.
Federal Building - Room 1C04
NINCDS, NIH
Bethesda, Maryland 20892
(301) 496-1447

National Eye Institute

Peter A. Dudley, Ph.D.
Building 31 - Room 6A51
NEI, NIH
Bethesda, Maryland 20892
(301) 496-5983

National Institute of General
Medical Sciences

Vivian Dickson
Westwood Building - Room 925
NIGMS, NIH
Bethesda, Maryland 20892
(301) 496-7129

Alcohol, Drug Abuse, and Mental Health Administration

National Institute of Mental
Health

Ellen S. Stover, Ph.D.
Parklawn Building - Room 10-104
NIMH, ADAMHA
5600 Fishers Lane
Rockville, Maryland 20892
(301) 443-4337

National Institute of Allergy
and Infectious Diseases

Dorothy D. Sogn, M.D.
Westwood Building - Room 7A52
NIAID, NIH
Bethesda, Maryland 20892
(301) 496-8973

National Institute on Aging

Evan Hadley, M.D.
Building 31 - Room 5C21
NIA, NIH
Bethesda, Maryland 20892
(301) 496-1033

National Institute of Child Health
and Human Development

Gilman D. Grave, M.D.
Landow Building - Room 7C17
NICHD, NIH
Bethesda, Maryland 20892
(301) 496-5575

National Institute of
Environmental Health Sciences

Edward Gardner, Ph.D.
P.O. Box 12233
Research Triangle Park
North Carolina 27709
(919) 541-7724

National Institute on Alcohol
Abuse And Alcoholism

Helen Chao, Ph.D.
Parklawn Building - Room 14C17
NIAAA, ADAMHA
5600 Fishers Lane
Rockville, Maryland 20892
(301) 443-4223

ANNOUNCEMENT

BIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

P.T. 22, 48; K.W. 0710030, 0404000

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) of the National Institutes of Health announces the availability of postdoctoral fellowships to U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical, behavioral, and health sciences.

PROGRAMS FOR U.S. SCIENTISTS

SENIOR INTERNATIONAL FELLOWSHIPS. These fellowships offer opportunities to U.S. biomedical, behavioral, or health scientists to conduct research in a foreign institution. The program is for scientists who have established themselves in their chosen career in the United States and whose professional stature is well recognized by their peers and institutional officials.

The purpose of this program is to enhance the exchange of ideas and information about the latest advances in the health sciences, both basic and clinical, and to permit U.S. scientists to participate abroad in ongoing study or research in the health sciences.

Fellowships are awarded for a period of 3 to 12 months and provide stipend, travel, and living allowance.

FOREIGN-SUPPORTED FELLOWSHIPS. These fellowships are supported by specific foreign countries. They provide opportunities for scientists to conduct collaborative research in the country that provides funding.

The purpose of this program is to enhance the exchange of research experience and information in the biomedical, behavioral, and health sciences. The maximum period of support for all programs is 1 year and the minimum period of support varies with each program.

Participating countries are: FINLAND, FRANCE (CNRS AND INSERM), FEDERAL REPUBLIC OF GERMANY, IRELAND, NORWAY, SWEDEN, SWITZERLAND, AND TAIWAN.

PROGRAM FOR FOREIGN SCIENTISTS

INTERNATIONAL RESEARCH FELLOWSHIPS. These fellowships offer opportunities to foreign scientists in the formative stage of their research career to extend their research experience in a U.S. laboratory. Selections are first made by the Nominating Committee in a participating country or region. Over 50 countries or regions in the Americas, Africa, Asia and the Far East, Australia, Europe, and New Zealand participate in the program.

The purpose of this program is to forge relationships between distinguished scientists in the United States and qualified scientists in other countries in order to solve health-related problems of mutual interest.

Fellowships are awarded for a minimum of 12 months and provide stipend, travel, and institutional allowance.

PROGRAM FOR EXCHANGE VISITS

HEALTH SCIENTIST EXCHANGES. This program supports short-term (2-12 weeks) exchange visits between the United States and HUNGARY, POLAND, ROMANIA, YUGOSLAVIA, OR THE SOVIET UNION.

The purpose of this program is to conduct collaborative activities in one of the health sciences or the health-related fields that are of mutual benefit to the United States and the participating country. Priority is given to visits designed to strengthen or expand ongoing collaborative relationships or to explore prospects for long-term cooperation.

The financial provisions include round-trip travel and in-country costs.

APPLICATION PROCEDURES

The eligibility requirements of each program vary and this information is provided in each program's brochure which is available upon request. However, at a minimum, each candidate must have an earned doctoral degree in one of the behavioral, biomedical, or health sciences and some postdoctoral experience. While the maximum period of support for all programs is 1 year, the minimum period of support varies with each program.

Application receipt dates for Senior International Fellowships are January 10, May 10, and September 10. Application kits are available only from the dean or equivalent institutional official. Only these persons can request the application kits from the FIC.

Applications to the Health Scientist Exchange Program, the Alexander von Humboldt Foundation, and the Visiting Scientists Program for the National Science Council, Taiwan, are available and are accepted throughout the year. Applications to all other foreign-supported fellowships must be submitted by May 10, 1986. These application kits are available from the FIC between 1 December and 30 April.

Prospective applicants for the International Research Fellowship Program must contact the Nominating Committee in their respective country for information and application procedure. Application kits are available only through the Nominating Committee. The Nominating Committees submit their applications to the FIC annually by August 1.

The National Institutes of Health is responsible for the scientific review of all applications except those that are submitted to the Alexander von Humboldt Foundation and the National Science Council, Taiwan.

You must send to the Fogarty International Center a self-addressed label if you need additional information. All correspondence should refer clearly to the specific program of interest.

Requests for additional information about the Health Scientist Exchange Programs should be sent to:

International Coordination and Liaison Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20892

All other requests should be sent to:

International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20892

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NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

I N D E X

VOLUME 1, NO. 1, APRIL 30, 1970

THROUGH

VOLUME 14, NO. 2, FEBRUARY 1, 1985

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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